

EXHIBIT 29



PART 4



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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13/826,880

03/14/2013

Stephen Donald WILTON

AVN-008CN15

2179

959

7590

09/11/2013

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EXAMINER

CHONG, KIMBERLY

ART UNIT

PAPER NUMBER

1635

MAIL DATE

DELIVERY MODE

09/11/2013

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action SummaryApplication No.
13/826,880Applicant(s)
WILTON ET AL.Examiner
KIMBERLY CHONGArt Unit
1635AIA (First Inventor to File)
Status
No**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03/14/2013.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-20 is/are pending in the application.
 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☐ Claim(s) ____ is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some * c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date ____.
- 3) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. ____.
- 4) ☐ Other: ____.

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The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-19, drawn to an antisense oligonucleotide having a sequence selected from SEQ ID Nos. 1-212 wherein the oligonucleotide specifically hybridizes to a target region in an exon of the human dystrophin gene, classifiable in class 536, subclass 24.5. **This group is subject to a further restriction of nucleotide sequences and a specific exon.**
- II. Claim 20, drawn to a method of treating Duchenne muscular dystrophy comprising administering a pharmaceutical composition comprising an oligonucleotide specifically hybridizes to a target region in an exon of the human dystrophin gene, classifiable in class 514, subclass 44. **This group is subject to a further restriction of nucleotide sequences and a specific exon.**

The inventions are distinct, each from the other because of the following reasons:

Inventions Groups I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

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process of using that product. See MPEP § 806.05(h). In the instant case the antisense oligonucleotide of Group I can be used in a materially different process such as an *in situ* hybridization assay. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

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Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Furthermore, should applicants elect to prosecute groups I or II, these groups are subject to further restriction as follows. Claims 1 and 2 are subject to an additional restriction since it is not considered to be a proper genus/Markush. See MPEP 803.02 – PRACTICE RE MARKUSH-TYPE CLAIMS – if the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claims on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 300 (CCPA 1980); and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. In *re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structure feature disclosed as being essential to that utility.

Claim 1 specifically claims nucleotide sequences having SEQ ID Nos. 1-212. Each nucleotide sequence is considered to be unrelated, since each sequence claimed

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is structurally and functionally distinct because each sequence targets a different exon or region of an exon thus modulating each exon differently. Furthermore, a search of more than one (1) of the sequences claimed in claim 1 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed sequences. In view of the foregoing, one (1) sequence is considered to be a reasonable number of sequences for examination. Accordingly, applicants are required to elect a total of one (1) sequence from claim 1. **Note that this is not a species election.**

Claim 2 specifically claims different exons. Each exon is considered to be unrelated, since each exon claimed is structurally and functionally distinct and would be modulated differently by distinct nucleotide sequences. Furthermore, a search of more than one (1) of the exons claimed in claim 2 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed exons. In view of the foregoing, one (1) exon is considered to be a reasonable number of sequences for examination. Accordingly, applicants are required to elect a total of one (1) exon from claim 2. **Note that this is not a species election.**

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing

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the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are

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subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 9-5 pm.

If attempts to reach the examiner by telephone are unsuccessful please contact the Acting SPE for 1635 Heather Calamita at 571-272-2876. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has

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been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Kimberly Chong/
Primary Examiner
Art Unit 1635



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/829,545	03/14/2013	Peter SAZANI	AVN-009CN	1561
123147	7590	06/06/2014		
Nelson Mullins Riley & Scarborough LLP/Sarepta One Post Office Square Boston, MA 02109			EXAMINER MCDONALD, JENNIFER SUE PITRAK	
			ART UNIT 1674	PAPER NUMBER
			NOTIFICATION DATE 06/06/2014	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipboston.docketing@nelsonmullins.com
chris.schlauch@nelsonmullins.com
ipqualityassuranceboston@nelsonmullins.com

Office Action SummaryApplication No.
13/829,545Applicant(s)
SAZANI ET AL.Examiner
JENNIFER PITRAK MCDONALDArt Unit
1674AIA (First Inventor to File)
Status
No**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/14/2013.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 1-19 is/are pending in the application.
5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-19 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 3/14/2013 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date ____.
- 3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 4) ☐ Other: ____.

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The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

Notice to Comply with 37 CFR §§ 1.821—1.825

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the following reason(s): The figures contain nucleic acid sequences that are not referenced by a corresponding sequence identifier ("SEQ ID NO:___"). For example, Figure 2D recites the entire sequence referred to as "Exon 51", but does not properly refer to the entire sequence with a corresponding sequence identifier. The same deficiency exists in Figures 3B and 4B.

To be considered fully responsive, any reply to this action must address these deficiencies, as this requirement will not be held in abeyance.

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 18, 19, and 20 have been renumbered 17, 18, and 19, respectively.

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Drawings

The drawings are objected to because several of the figures contain nucleic acid sequences not properly referenced by a corresponding sequence identifier. See above for details. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of 35 U.S.C. 112(b):

(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim 16 is rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention. Claim 16 depends from a non-existent claim. Therefore, the metes and bounds of claim 16 cannot be ascertained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of pre-AIA 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 13, 14, 15, 17, 18, and 19 are rejected under pre-AIA 35 U.S.C. 102(b) as being anticipated by Wilton, et al. (WO/2006/000057; published January 05, 2006) ("Wilton").

Wilton teaches isolated antisense compounds that are 20 nucleotides in length comprising 20 consecutive nucleotides of the instant SEQ ID NO:17 and SEQ ID NO:4 (p.15, Table 1A, SEQ ID NOs: 166 and 167). Wilton teaches that the invention includes such oligonucleotides linked to conjugates including PEG or polyamine or comprised of uncharged PNA (pages 26-27). Wilton teaches methods of treating Duchenne Muscular Dystrophy (DMD) comprising administering to a patient in need thereof an effective amount of a pharmaceutical composition comprising the disclosed antisense oligonucleotides. Therefore, Wilton anticipates the instant claims 1-4, 13-15, 17, 18, and 19.

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Claim Rejections - 35 USC § 103

The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under pre-AIA 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under pre-AIA 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of pre-AIA 35 U.S.C. 103(c) and potential pre-AIA 35 U.S.C. 102(e), (f) or (g) prior art under pre-AIA 35 U.S.C. 103(a).

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Claims 1-15, 17, 18, and 19 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Wilton, et al. (WO/2006/000057; published January 05, 2006) ("Wilton").

Wilton teaches isolated antisense compounds that are 20 nucleotides in length comprising 20 consecutive nucleotides of the instant SEQ ID NO:17 and SEQ ID NO:4 (p.15, Table 1A, SEQ ID NOs: 166 and 167). Wilton teaches that the invention includes such oligonucleotides linked to conjugates including PEG or polyamine or comprised of uncharged PNA (pages 26-27). Wilton teaches methods of treating Duchenne Muscular Dystrophy (DMD) comprising administering to a patient in need thereof an effective amount of a pharmaceutical composition comprising the disclosed antisense oligonucleotides. Therefore, the instant claims 1-4, 13, 14, 15, 17, 18, and 19 are obvious over Wilton.

Wilton also teaches that the oligonucleotides of the invention may comprise morpholino subunits linked by charged or uncharged phosphorus-containing intersubunit linkages. Wilton teaches that the oligonucleotides may comprise internucleotide linkages modified with a cationic group and that every other linkage in a given oligonucleotide is charged or uncharged (Tables 1A and 1B; pp.25-27).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the instant invention was made to make an antisense oligonucleotide according to the instant claims 5-12 because Wilton teaches that such oligonucleotides are within the scope of the invention and that those of skill in the art are apprised of methods of making them (pp.25-26). One of ordinary skill in the art, provided with the guidance of Wilton, would be able to make the instantly claimed oligonucleotides by no more than routine optimization and experimentation and would have been motivated to do so because Wilton suggests doing so. Therefore, the instant claims

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would have been *prima facie* obvious to one of ordinary skill in the art at the time of the instant invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used.

Application/Control Number: 13/829,545
Art Unit: 1635

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Please visit <http://www.uspto.gov/forms/>. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to <http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp>.

Claims 1-19 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 66 and 68-81 of copending Application No. 12/605276. Although the claims at issue are not identical, they are not patentably distinct from each other because the claims of the '276 application are directed to an anticipatory species of the instant claims.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

Claims 1-19 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1 and 4-23 of copending Application No. 13/830253. Although the claims at issue are not identical, they are not patentably distinct from each other because the claims of the '253 application anticipate the instant claims.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER PITRAK MCDONALD whose telephone number is

Application/Control Number: 13/829,545
Art Unit: 1635

Page 9

(571)270-3061. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Babic can be reached on 571-272-8507. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JENNIFER PITRAK MCDONALD/
Primary Examiner, Art Unit 1635



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

123147 7590 06/11/2014
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

EXAMINER	
MCDONALD, JENNIFER SUE PITRAK	
ART UNIT	PAPER NUMBER
1674	

DATE MAILED: 06/11/2014

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

13/830,253 03/14/2013 Peter SAZANI AVN-009CN2 2760

TITLE OF INVENTION: MULTIPLE EXON SKIPPING COMPOSITIONS FOR DMD

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$480	\$0	\$0	\$480	09/11/2014

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: **Mail****Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885**

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

123147 7590 06/11/2014
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/830,253	03/14/2013	Peter SAZANI	AVN-009CN2	2760

TITLE OF INVENTION: MULTIPLE EXON SKIPPING COMPOSITIONS FOR DMD

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$480	\$0	\$0	\$480	09/11/2014

EXAMINER	ART UNIT	CLASS-SUBCLASS
MCDONALD, JENNIFER SUE PITRAK	1674	536-024500

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ Applicant certifying micro entity status. See 37 CFR 1.29
☐ Applicant asserting small entity status. See 37 CFR 1.27
☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/830,253	03/14/2013	Peter SAZANI	AVN-009CN2	2760

EXAMINER
MCDONALD, JENNIFER SUE PITRAK

ART UNIT	PAPER NUMBER
1674	

DATE MAILED: 06/11/2014

123147 7590 06/11/2014
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 13/830,253	Applicant(s) SAZANI ET AL.	
	Examiner JENNIFER PITRAK MCDONALD	Art Unit 1674	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicant's 5/27/2014 submission.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are 1 and 4-23. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a) ☐ All b) ☐ Some *c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____ 3. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material 4. <input type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date _____	5. <input type="checkbox"/> Examiner's Amendment/Comment 6. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 7. <input type="checkbox"/> Other _____
---	---

/JENNIFER PITRAK MCDONALD/
Primary Examiner, Art Unit 1674

Application/Control Number: 13/830,253
Art Unit: 1674

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The present application is being examined under the pre-AIA first to invent provisions.

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance: The instant claims are free of the art and are deemed to meet the statutory requirements of 35 USC §§ 101, 102, 103, and 112.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER PITRAK MCDONALD whose telephone number is (571)270-3061. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Babic can be reached on 571-272-8507. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JENNIFER PITRAK MCDONALD/
Primary Examiner, Art Unit 1674



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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13/830,253

03/14/2013

Peter SAZANI

AVN-009CN2

2760

959

7590

11/26/2013

NELSON MULLINS RILEY & SCARBOROUGH LLP
FLOOR 30, SUITE 3000
ONE POST OFFICE SQUARE
BOSTON, MA 02109

EXAMINER

MCDONALD, JENNIFER SUE PITRAK

ART UNIT

PAPER NUMBER

1635

MAIL DATE

DELIVERY MODE

11/26/2013

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action SummaryApplication No.
13/830,253Applicant(s)
SAZANI ET AL.Examiner
JENNIFER PITRAK MCDONALDArt Unit
1635AIA (First Inventor to File)
Status
No**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/14/2013.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 1-19 is/are pending in the application.
5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-19 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 3/14/2013 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date ____.
- 3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 4) ☐ Other: ____.

Application/Control Number: 13/830,253
Art Unit: 1635

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DETAILED ACTION

Notice to Comply with 37 CFR §§ 1.821—1.825

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the following reason(s): The figures contain nucleic acid sequences that are not referenced by a corresponding sequence identifier ("SEQ ID NO:___"). For example, Figure 2D recites the entire sequence referred to as "Exon 51", but does not properly refer to the entire sequence with a corresponding sequence identifier. The same deficiency exists in Figures 3B and 4B.

To be considered fully responsive, any reply to this action must address these deficiencies, as this requirement will not be held in abeyance.

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 18, 19, and 20 have been renumbered 17, 18, and 19, respectively.

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Drawings

The drawings are objected to because several of the figures contain nucleic acid sequences not properly referenced by a corresponding sequence identifier. See above for details. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of 35 U.S.C. 112(b):

(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim 16 is rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention. Claim 16 depends from a non-existent claim. Therefore, the metes and bounds of claim 16 cannot be ascertained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of pre-AIA 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 13, 14, 15, 17, 18, and 19 are rejected under pre-AIA 35 U.S.C. 102(b) as being anticipated by Wilton, et al. (WO/2006/000057; published January 05, 2006) ("Wilton").

Wilton teaches isolated antisense compounds that are 20 nucleotides in length comprising 20 consecutive nucleotides of the instant SEQ ID NO:17 and SEQ ID NO:4 (p.15, Table 1A, SEQ ID NOs: 166 and 167). Wilton teaches that the invention includes such oligonucleotides linked to conjugates including PEG or polyamine or comprised of uncharged PNA (pages 26-27). Wilton teaches methods of treating Duchenne Muscular Dystrophy (DMD) comprising administering to a patient in need thereof an effective amount of a pharmaceutical composition comprising the disclosed antisense oligonucleotides. Therefore, Wilton anticipates the instant claims 1-4, 13-15, 17, 18, and 19.

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Claim Rejections - 35 USC § 103

The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under pre-AIA 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under pre-AIA 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of pre-AIA 35 U.S.C. 103(c) and potential pre-AIA 35 U.S.C. 102(e), (f) or (g) prior art under pre-AIA 35 U.S.C. 103(a).

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Claims 1-15, 17, 18, and 19 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Wilton, et al. (WO/2006/000057; published January 05, 2006) ("Wilton").

Wilton teaches isolated antisense compounds that are 20 nucleotides in length comprising 20 consecutive nucleotides of the instant SEQ ID NO:17 and SEQ ID NO:4 (p.15, Table 1A, SEQ ID NOs: 166 and 167). Wilton teaches that the invention includes such oligonucleotides linked to conjugates including PEG or polyamine or comprised of uncharged PNA (pages 26-27). Wilton teaches methods of treating Duchenne Muscular Dystrophy (DMD) comprising administering to a patient in need thereof an effective amount of a pharmaceutical composition comprising the disclosed antisense oligonucleotides. Therefore, the instant claims 1-4, 13, 14, 15, 17, 18, and 19 are obvious over Wilton.

Wilton also teaches that the oligonucleotides of the invention may comprise morpholino subunits linked by charged or uncharged phosphorus-containing intersubunit linkages. Wilton teaches that the oligonucleotides may comprise internucleotide linkages modified with a cationic group and that every other linkage in a given oligonucleotide is charged or uncharged (Tables 1A and 1B; pp.25-27).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the instant invention was made to make an antisense oligonucleotide according to the instant claims 5-12 because Wilton teaches that such oligonucleotides are within the scope of the invention and that those of skill in the art are apprised of methods of making them (pp.25-26). One of ordinary skill in the art, provided with the guidance of Wilton, would be able to make the instantly claimed oligonucleotides by no more than routine optimization and experimentation and would have been motivated to do so because Wilton suggests doing so. Therefore, the instant claims

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would have been *prima facie* obvious to one of ordinary skill in the art at the time of the instant invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

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The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit <http://www.uspto.gov/forms/>. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to <http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp>.

Claims 1-19 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 66 and 68-81 of copending Application No. 12/605276. Although the claims at issue are not identical, they are not patentably distinct from each other because the claims of the '276 application are directed to an anticipatory species of the instant claims.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER PITRAK MCDONALD whose telephone number is (571)270-3061. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Babic can be reached on 571-272-8507. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JENNIFER PITRAK MCDONALD/
Primary Examiner, Art Unit 1635



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/902,376	05/24/2013	Stephen Donald WILTON	AVN-008CN17 / TRACK1	4184
123147	7590	06/05/2014	EXAMINER	
Nelson Mullins Riley & Scarborough LLP/Sarepta One Post Office Square Boston, MA 02109			CHONG, KIMBERLY	
			ART UNIT	PAPER NUMBER
			1674	
			NOTIFICATION DATE	DELIVERY MODE
			06/05/2014	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipboston.docketing@nelsonmullins.com
chris.schlauch@nelsonmullins.com
ipqualityassuranceboston@nelsonmullins.com

Office Action SummaryApplication No.
13/902,376Applicant(s)
WILTON ET AL.Examiner
KIMBERLY CHONGArt Unit
1674AIA (First Inventor to File)
Status
No**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03/21/2014.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 2 and 4-13 is/are pending in the application.
5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 2 and 4-13 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date 03/21/2014.
- 3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 4) ☐ Other: ____.

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The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed 03/21/2014 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 01/07/2014 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

With entry of the amendment filed on 01/07/2014, claims 2 and 4-13 are pending and currently under examination.

Information Disclosure Statement

The submission of the Information Disclosure Statement on 03/21/2014 is in compliance with 37 CFR 1.97. The information disclosure statement has been considered by the examiner and signed copies have been placed in the file.

Claim Objections

Claims 5-8 and 10-13 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the

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claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims depend from claim 4 and 9 which recite a nucleotide sequence comprising purine and pyrimidine bases and thus fail to further limit the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of 35 U.S.C. 112(b):

(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-8 and 10-13 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

Claims 5-8 and 10-13 recite a nucleotide sequence comprising purine and pyrimidine bases and thus infers that claims 4 and 9 have other bases besides purine and pyrimidine and it is unclear what other types of bases would be included in this recitation which makes the claims indefinite.

Claims 6 and 11 recite the bases of said nucleotides of said oligonucleotide, other than the bases of SEQ ID No. 192, consist of purine and pyrimidine bases. It is unclear what is meant by the bases other than the bases of the claimed sequence consist of purine and pyrimidine because the claimed sequence does in fact consist of

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purine and pyrimidine. Further, it is unclear what other nucleotides would be included in the claim and therefore the claims are indefinite.

The following is a quotation of the first paragraph of 35 U.S.C. 112(a):

(a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of the first paragraph of pre-AIA 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6 and 9-13 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or for pre-AIA the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 9-13 are drawn to an oligonucleotide that is complementary to a target sequence wherein the target sequence consists of a nucleotide sequence that is complementary to SEQ ID No. 192. This limitation includes terminology not present in the instant application as filed and involves an addition to the disclosure and thus written description is lacking.

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Applicant points to page 65, lines 5-14 for support. The specification at page 65 discloses antisense oligonucleotides directed to exon 53. There is no disclosure of the target sequence consisting of a target sequence that is complementary to SEQ ID No. 192.

Claims 6 and 11 are drawn to an oligonucleotide wherein the bases, other than SEQ ID NO. 192 consist of purine and pyrimidine. Applicant points to page 17, lines 1-5 and page 27, lines 7-14 for support. There is no support on these pages or any other page in the specification that provides adequate written description for the claimed oligonucleotide as recited.

If Applicant believes that such support is present in the specification and claimed priority documents, Applicant should point, with particularity, to where such support is to be found. Therefore, the effective filing date of claims 6 and 9-13 is considered, for purposes of prior art to be 05/24/2013, which is the filing date of the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of pre-AIA 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claims 6 and 9-13 are rejected under pre-AIA 35 U.S.C. 102(b) as being anticipated by van Ommen (US Application 20060147952 cited on IDS filed 03/20/2014) and evidence by Matsuo et al. (US 6,653,467).

Claims 2, 4, 5, 7 and 8 are rejected under pre-AIA 35 U.S.C. 102(e) as being anticipated by van Ommen (US Application 20060147952 cited on IDS filed 03/20/2014) and evidence by Matsuo et al. (US 6,653,467).

The claims are drawn to an isolated antisense oligonucleotide of 15-80 nucleotides comprising at least 15 or 20 bases of SEQ ID No. 192, wherein said oligonucleotide induces exon 53 skipping and comprise modifications and drawn to an isolated oligonucleotide of 18-80 nucleotides in length comprising a nucleotide sequence that is complementary to the sequence having SEQ ID No. 192, wherein said oligonucleotide comprises modifications and drawn to an oligonucleotide 18-80 nucleotides in length complementary to a target sequence wherein the target sequence consists of a sequence that is complementary to SEQ ID No. 192.

van Ommen teach an oligonucleotide having SEQ ID No. 29 that is 18 nucleotides in length that is identical to the claimed SEQ ID No. 192. van Ommen teach the oligonucleotide can comprise modified nucleotides such as 2'-O-methyl, a morpholine ring, peptide nucleic acids and locked nucleic acids (see paragraph 0019).

van Ommen teach in [0018] oligonucleotides that are complementary to a consecutive part of between 16 and 50 nucleotides of an exon RNA and teach different types of nucleic acid molecules can be used to generate the oligonucleotide.

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[0020] The complementary oligonucleotide generated through a method of the invention is preferably complementary to a consecutive part of between 16 and 50 nucleotides of the exon RNA. Different types of nucleic acid may be used to generate the oligonucleotide.

van Ommen teach in [0015 and 0016] the use of oligonucleotides to skip exons such as exon 53. In paragraph [0019] it is taught that the oligonucleotide can have modifications such as morpholino phosphorodiamidate, peptide nucleic acid and locked nucleic acids, for example, and further teach the oligonucleotide comprises modified internucleoside linkages.

[0019] With the advent of nucleic acid-mimicking technology, it has become possible to generate molecules that have a similar, preferably the same, hybridization characteristics, in kind, not necessarily in amount, as nucleic acid itself. Such equivalents are, of course, also part of the invention. Examples of such mimics equivalents are peptide nucleic acid, locked nucleic acid and/or a morpholino phosphorodiamidate...Hybrids between one or more of the equivalents among each other and/or together with nucleic acid are, of course, also part of the invention. In a preferred embodiment, an equivalent comprises locked nucleic acid, as locked nucleic acid displays a higher target affinity and reduced toxicity and, therefore, shows a higher efficiency of exon skipping.

van Ommen teach in [0018] that the oligonucleotide preferably comprises RNA, which would mean that the oligonucleotide is also DNA. Thus while van Ommen teach a preferred embodiment of RNA oligonucleotides, DNA oligonucleotides are also taught and finds support on page 10 of the specification which discusses examples of DNA oligonucleotides known in the prior art e.g. oligonucleotides containing locked nucleic acids (DNA analogs). As evidenced by Matsuo et al., the term "oligonucleotide" is known in the art to as DNA or RNA (see column 9).

MPEP 2123 states in part:

A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. Merck & Co. v. Biocraft Laboratories, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989).

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See also > *Upsher-Smith Labs. v. PamLab, LLC*, 412 F.3d 1319, 1323, 75 USPQ2d 1213, 1215 (Fed. Cir. 2005)(reference disclosing optional inclusion of a particular component teaches compositions that both do and do not contain that component); < *Celeritas Technologies Ltd. v. Rockwell International Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998) (The court held that the prior art anticipated the claims even though it taught away from the claimed invention. "The fact that a modem with a single carrier data signal is shown to be less than optimal does not vitiate the fact that it is disclosed."). {emphasis added}

Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." In re Gurley, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994) (The invention was directed to an epoxy impregnated fiber-reinforced printed circuit material. The applied prior art reference taught a printed circuit material similar to that of the claims but impregnated with polyester-imide resin instead of epoxy. The reference, however, disclosed that epoxy was known for this use, but that epoxy impregnated circuit boards have "relatively acceptable dimensional stability" and "some degree of flexibility," but are inferior to circuit boards impregnated with polyester-imide resins. The court upheld the rejection concluding that applicant's argument that the reference teaches away from using epoxy was insufficient to overcome the rejection since "Gurley asserted no discovery beyond what was known in the art." 27 F.3d at 554, 31 USPQ2d at 1132.). Furthermore, "[t]he prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed..." In re Fulton, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004). {emphasis added}.

van Ommen reasonably teach to one having ordinary skill in the art nonpreferred embodiments of DNA oligonucleotides that are complementary to a target sequence of exon 53.

With respect to instantly claimed 2 reciting an oligonucleotide comprising at least 20 bases of SEQ ID No. 192, van Ommen teach a genus of oligonucleotides targeted to exon 53 wherein the oligonucleotides are complementary to a consecutive part of between 16 and 50 nucleotides of an exon 53 (see 0018). MPEP 2131.02 states that if

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one of ordinary skill in the art is able to “at once envisage” the specific compound within a genus, the compound is anticipated.

2131.02 Genus-Species Situations [R-11.2013]

III. A GENERIC DISCLOSURE WILL ANTICIPATE A CLAIMED SPECIES COVERED BY THAT DISCLOSURE WHEN THE SPECIES CAN BE “AT ONCE ENVISAGED” FROM THE DISCLOSURE

“[W]hether a generic disclosure necessarily anticipates everything within the genus ... depends on the factual aspects of the specific disclosure and the particular products at issue.” *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1083, 89 USPQ2d 1370, 1375 (Fed. Cir. 2008). See also *Osram Sylvania Inc. v. American Induction Tech.*, 701 F.3d 698, 706, 105 USPQ2d 1368, 1374 (Fed. Cir. 2012) (“how one of ordinary skill in the art would understand the relative size of a genus or species in a particular technology is of critical importance”).

For example, when a claimed compound is not specifically named in a reference, but instead it is necessary to select portions of leachings within the reference and combine them, e.g., select various substituents from a list of alternatives given for placement at specific sites on a generic chemical formula to arrive at a specific composition, anticipation can only be found if the classes of substituents are sufficiently limited or well delineated. *Ex parte A*, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990). If one of ordinary skill in the art is able to “at once envisage” the specific compound within the generic chemical formula, the compound is anticipated. One of ordinary skill in the art must be able to draw the structural formula or write the name of each of the compounds included in the generic formula before any of the compounds can be “at once envisaged.” One may look to the preferred embodiments to determine which compounds can be anticipated. *In re Petering*, 301 F.2d 676, 133 USPQ 275 (CCPA 1962).

Given that van Ommen et al. teach oligonucleotides of 16 to 50 nucleotides in length that are complementary to exon 53 and the sequence of exon 53 is known in the prior art and further teach an oligonucleotide having 18 identical nucleotides of the claimed SEQ ID No. 2, one of ordinary skill in the art is clearly able to envisage an

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oligonucleotide of at least 20 nucleotides, 2 nucleotides longer than taught by van Ommen et al., that is complementary to exon 53.

Thus van Ommen anticipates the instant claims.

Applicant has provided a detailed argument of why van Ommen is not prior art in anticipation of this reference being cited and thus in the interest of compact prosecution, the relevant arguments will be addressed.

Applicant states van Ommen and the claim amendments filed 01/22/2014 (which have been duplicated in the instant application) lack proper written description and thus is unsupported by the priority documents and is not prior art. Applicant argues van Ommen were only in possession of RNA oligonucleotides and not DNA oligonucleotides. As explained above van Ommen reasonably teach to one having ordinary skill in the art nonpreferred embodiments of DNA oligonucleotides.

Applicants argue oligonucleotides had an established meaning to those of ordinary skill in the art as of the date of the invention of the van Ommen application and as shown by Gerwitz (cited in the remarks filed 03/20/2014), which provides evidence that those of ordinary skill in the relevant art understood, the term oligonucleotide encompasses both DNA and RNA oligonucleotides, and further teach RNA and DNA oligonucleotides had different advantages and disadvantages and one of ordinary skill would understand that Gerwitz teach RNA oligonucleotides would be appropriate for exon skipping.

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This argument is not persuasive enough to ignore what the term "oligonucleotide" would mean to one of ordinary skill in the art. Gerwitz provides sufficient evidence, as acknowledged by Applicant, that one of ordinary skill in the relevant art would understand that oligonucleotide encompasses both RNA and DNA oligonucleotides. Thus with Gerwitz providing evidence that one would understand that an oligonucleotide encompasses both RNA and DNA oligonucleotides, van Ommen clearly teach DNA oligonucleotides.

Moreover, further evidence is provided in the prior art on what the term "oligonucleotide" would mean to one of ordinary skill in the art. As stated above, Matsuo et al. teach an oligonucleotide is known in the art as a DNA and RNA (see column 9).

Applicant further argues that the term complementary is not defined in the van Ommen specification to support the claimed invention because the term is defined to include mismatches. Again while van Ommen does state the complementary oligonucleotide can have mismatches to the target sequence, this is a preferred embodiment and the specification as a whole does not teach away from a complementary oligonucleotide targeted to exon 53 and one of skill in the art can readily identify complementary oligonucleotides to exon 53, wherein the target sequence would comprise nucleotides that are complementary to the oligonucleotide having SEQ ID No. 29.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

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unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2 and 4-13 are provisionally rejected under the judicially created doctrine of double patenting over claims 21-49 of copending Application No. 14/086,859. This is a provisional double patenting rejection since the conflicting claims have not yet been patented. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of the patent are drawn to patently indistinguishable subject matter.

Claims 2 and 4-13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-25 of U.S. Patent No. 8,232,384. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of the patent are drawn to patently indistinguishable subject matter.

Claims 2 and 4-13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-43 of U.S. Patent No. 8,455,636. Although the conflicting claims are not identical, they are not

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patentably distinct from each other because the instant claims and the claims of the patent are drawn to patently indistinguishable subject matter.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Kimberly Chong** whose telephone number is **571-272-3111**. The examiner can normally be reached Monday thru Friday between 9-5 pm.

If attempts to reach the examiner by telephone are unsuccessful please contact the SPE for 1674 Christopher Babic at 571-272-8507. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Kimberly Chong/
Primary Examiner
Art Unit 1674



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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13/902,376

05/24/2013

Stephen Donald WILTON

AVN-008CN17

4184

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01/07/2014

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EXAMINER

CHONG, KIMBERLY

ART UNIT

PAPER NUMBER

1674

MAIL DATE

DELIVERY MODE

01/07/2014

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action SummaryApplication No.
13/902,376Applicant(s)
WILTON ET AL.Examiner
KIMBERLY CHONGArt Unit
1674AIA (First Inventor to File)
Status
No**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/18/2013.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 2 and 3 is/are pending in the application.
 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 2,3 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
 Paper No(s)/Mail Date 10/18/2013.
- 3) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. ____.
- 4) ☐ Other: ____.

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The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed 10/18/2013 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 07/18/2013 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

With entry of the amendment filed on 10/18/2013, claims 2 and 3 are pending and currently under examination.

Information Disclosure Statement

The submission of the Information Disclosure Statement on 10/18/2013 is in compliance with 37 CFR 1.97. The information disclosure statement has been considered by the examiner and signed copies have been placed in the file.

New Claim Rejections

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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Claims 2 and 3 are rejected under 35 U.S.C. 101.

The claimed invention is directed to a naturally-occurring nucleic acid fragment thereof, whether isolated or not that is not patent-eligible pursuant to the Supreme Court decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.* -- U.S.-- (June 13, 2013). The claims read on unmodified naturally occurring nucleic acid that is a product of nature.

Thus the claims are not patent-eligible.

Response to Arguments

Claim Rejections - 35 USC § 112

The rejection of claim 2 under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention, is withdrawn in response to claim amendments.

Claim Rejections - 35 USC § 112

The rejection of claim 2 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in response to claim amendments.

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Claim Rejections - 35 USC § 102

The rejection of claims 2 and 3 under 35 U.S.C. 102(b) as being anticipated by van Ommen et al. (U.S. 20060147952 of record cited on IDS filed 05/31/2013) is withdrawn.

The rejection of claim 2 under 35 U.S.C. 102(b) as being anticipated by Moulton et al. (U.S. 20100016215) is withdrawn in response to claim amendments.

The rejection of claim 2 under 35 U.S.C. 102(b) as being anticipated by Sazani et al. (U.S. 20100130591) is withdrawn in response to claim amendments.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2 and 3 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No.

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8,455,636. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of the patent are drawn to patentably indistinguishable subject matter such as an antisense oligonucleotide targeted to exon 53.

Applicants request the rejection be held in abeyance until allowable claims are indicated.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Kimberly Chong** whose telephone number is **571-272-3111**. The examiner can normally be reached Monday thru Friday between 9-5 pm.

If attempts to reach the examiner by telephone are unsuccessful please contact the SPE for 1674 Christopher Babic at 571-272-8507. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

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/Kimberly Chong/
Primary Examiner
Art Unit 1674



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/902,376	05/24/2013	Stephen Donald WILTON	AVN-008CN17	4184

959 7590 07/18/2013
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BOSTON, MA 02109

EXAMINER

CHONG, KIMBERLY

ART UNIT	PAPER NUMBER
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1635

MAIL DATE	DELIVERY MODE
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07/18/2013

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action SummaryApplication No.
13/902,376Applicant(s)
WILTON ET AL.Examiner
KIMBERLY CHONGArt Unit
1635AIA (First Inventor to File)
Status
No**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 May 2013.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 2 and 3 is/are pending in the application.
5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 2 and 3 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 24 May 2013 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some * c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 05/31/2013.
- 3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 4) ☐ Other: ____.

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DETAILED ACTION

Status of the Application

Claims 2 and 3 are pending and currently under examination.

Information Disclosure Statement

The submission of the Information Disclosure Statement on 05/31/2013 is in compliance with 37 CFR 1.97. The information disclosure statement has been considered by the examiner and signed copies have been placed in the file.

Claim Rejections - 35 USC § 112

The following is a quotation of 35 U.S.C. 112(b):

(B) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

Claim 2 recites “an equivalent oligonucleotide” and it is unclear what is meant by an equivalent oligonucleotide. The specification does not define what an equivalent oligonucleotide encompasses and one of ordinary skill in the art

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would not be reasonably apprised of the scope of the claimed equivalent oligonucleotide. It is unclear if the equivalent oligonucleotide has the same sequence but includes modified nucleotides, or an equivalent oligonucleotide has the same function as SEQ ID No. 192 but not the same sequence.

For examination purposes, an equivalent oligonucleotide is given its broadest reasonable interpretation and is interpreted as any oligonucleotide with a base substitution of a U by a T. The equivalent oligonucleotide is interpreted such that it does not have to have the claimed SEQ ID No. 192.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 2 is drawn to an “equivalent oligonucleotide” or “said oligonucleotide or its equivalent”. The priority documents such as 11/570,691 now Patent 7,807,816 do not provide adequate support for an equivalent oligonucleotide of

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SEQ ID No. 192. If Applicant believes that such support is present in the specification and claimed priority documents, Applicant should point, with particularity, to where such support is to be found.

Therefore, the effective filing date of claim 2 is considered, for purposes of prior art to be 05/24/2013, which is the filing date of the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by van Ommen et al. (U.S. 20060147952 of record cited on IDS filed 05/31/2013).

Claim 2 is drawn to an isolated antisense oligonucleotide of 20 to 50 nucleotides comprising at least 17 consecutive nucleotides of base sequence SEQ ID No. 192 or an equivalent oligonucleotide comprising a modification, wherein said oligonucleotide induces exon 53 skipping of the human dystrophin pre-mRNA, and wherein the modification comprises a base substitution of a U by a T.

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Claim 3 is drawn to an isolated antisense oligonucleotide of 24 to 50 nucleotides in length comprising a sequence which is complementary to a target nucleic acid sequence of human exon 53 pre-mRNA, wherein the target nucleic acid sequence comprises a 24 nucleotide sequence that is complementary to SEQ ID No. 192 and wherein the oligonucleotide comprising a modification, said modification comprising a base substitution of a U by a T.

Claim 3 interpretation:

Claim 3 is interpreted such that it requires at least an antisense oligonucleotide of 24 nucleotides in length that is complementary to human exon 53. The claim as recited does not require the oligonucleotide to specifically target the nucleic acid region that is complementary to SEQ ID No. 193. The target nucleic acid sequence comprises a region complementary to SEQ ID No. 194 but does not necessarily require the oligonucleotide to target that specific region. The oligonucleotide does not comprise a required sequence such as SEQ ID No. 192 and is only required to be complementary to any region of human exon 53.

van Ommen et al teach an oligonucleotide of 15 to 80 nucleotides comprising at least 15 nucleotides of SEQ ID No. 29 which is an 18 mer oligonucleotide having the sequence CUGUUGCCUCCGGUUCUG. SEQ ID No. 29 comprises 18 nucleotides of the instantly claimed oligonucleotide having SEQ ID No. 192. van Ommen et al. teach the oligonucleotide binds to exon 53 and is

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capable of skipping exon 53 (see at least Table 2), which meets the claim limitations of claim 3.

van Ommen et al. teach in paragraph [0018-0019] that the oligonucleotide can comprise different types of nucleic acids (which would be DNA or RNA) and teach modifications such as peptide nucleic acids or morpholinos. Table 1A in the instant specification teach substitution of a U by a T would be using other antisense chemistries such as peptide nucleic acids or morpholinos (TABLE-US-00001 [0051] TABLE 1A Description of 2'-O-methyl phosphorothioate antisense oligonucleotides that have been used to date to study induced exon skipping during the processing of the dystrophin pre-mRNA. Since these 2'-O-methyl antisense oligonucleotides are more RNA-like, U represents uracil. With other antisense chemistries such as peptide nucleic acids or morpholinos, these U bases may be shown as "T").

Thus van Ommen et al. anticipates the instant claim.

Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Moulton et al. (U.S. 20100016215).

Claim 2 is drawn to an isolated antisense oligonucleotide of 20 to 50 nucleotides comprising at least 17 consecutive nucleotides of base sequence SEQ ID No. 192 or an equivalent oligonucleotide comprising a modification, wherein said oligonucleotide induces exon 53 skipping of the human dystrophin pre-mRNA, and wherein the modification comprises a base substitution of a U by a T.

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Moulton et al. teach an oligonucleotide 24 nucleotides in length that comprises base substitutions of a U by a T (see sequence below).

SEQ ID No. 192 1 CUGUUGCCUCCGGUUCUGAAGGUG 24

SEQ ID No. 29 1 CTGTTGCCTCCGGTTCTGAAGGTG 24

Based on the interpretation of an equivalent nucleotide above, Moulton et al. anticipates the instant claim.

Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Sazani et al. (U.S. 20100130591).

Claim 2 is drawn to an isolated antisense oligonucleotide of 20 to 50 nucleotides comprising at least 17 consecutive nucleotides of base sequence SEQ ID No. 192 or an equivalent oligonucleotide comprising a modification, wherein said oligonucleotide induces exon 53 skipping of the human dystrophin pre-mRNA, and wherein the modification comprises a base substitution of a U by a T.

Sazani et al. teach an oligonucleotide 25 nucleotides comprising 24 identical nucleotides of SEQ ID No. 192 and comprising base substitutions of a U by a T (see sequence below).

SEQ ID No. 192 1 CUGUUGCCUCCGGUUCUGAAGGUG 24

SEQ ID No. 29 1 CTGTTGCCTCCGGTTCTGAAGGTG 24

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The oligonucleotide taught by Sazani et al. meets the structural limitations of the claims and thus would induce exon 53 skipping, absent evidence to the contrary.

The MPEP states:

A REFERENCE TEACHING PRODUCT APPEARING TO BE SUBSTANTIALLY IDENTICAL IS MADE THE BASIS OF A REJECTION, AND THE EXAMINER PRESENTS EVIDENCE OR REASONING TENDING TO SHOW INHERENCY, THE BURDEN SHIFTS TO THE APPLICANT TO SHOW AN UNOBVIOUS DIFFERENCE

"[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency' under 35 U.S.C. 102, on prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. *In re Fitzgerald*, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).

MPEP 2112.01:

PRODUCT AND APPARATUS CLAIMS □ WHEN THE STRUCTURE RECITED IN THE REFERENCE IS SUBSTANTIALLY IDENTICAL TO THAT OF THE CLAIMS, CLAIMED PROPERTIES OR FUNCTIONS ARE PRESUMED TO BE INHERENT

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). □ When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not. □ *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433.

A REJECTION UNDER 35 U.S.C. 102/103 CAN BE MADE WHEN THE PRIOR ART PRODUCT SEEMS TO BE IDENTICAL EXCEPT THAT THE PRIOR ART IS SILENT AS TO AN INHERENT CHARACTERISTIC

Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. "There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102." *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims.

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Thus Sazani et al. anticipates the instant claim.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2 and 3 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 8,455,636. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of the patent are drawn to patently indistinguishable subject matter such as an antisense oligonucleotide targeted to exon 53.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Kimberly Chong** whose telephone number is

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571-272-3111. The examiner can normally be reached Monday thru Friday between 9-5 pm.

If attempts to reach the examiner by telephone are unsuccessful please contact the SPE for 1635 Heather Calamita at 571-272-2876. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Kimberly Chong/
Primary Examiner
Art Unit 1635



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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13/963,578

08/09/2013

Stephen Donald WILTON

AVN-008CN18

2110

959

7590

09/24/2013

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EXAMINER

CHONG, KIMBERLY

ART UNIT

PAPER NUMBER

1635

MAIL DATE

DELIVERY MODE

09/24/2013

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action SummaryApplication No.
13/963,578Applicant(s)
WILTON ET AL.Examiner
KIMBERLY CHONGArt Unit
1635AIA (First Inventor to File)
Status
No**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08/09/2013.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-24 is/are pending in the application.
5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☐ Claim(s) ____ is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some * c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.

- 3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 4) ☐ Other: ____.

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The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, 9-24, drawn to an antisense oligonucleotide capable of binding to a selected target site to induce exon skipping as set for in SEQ ID Nos. 1-202, classifiable in class 536, subclass 24.5. This group is subject to a further restriction of an exon and corresponding antisense molecule.
- II. Claim 8, drawn to a method of treating muscular dystrophy in a patient comprising administering a composition comprising an antisense oligonucleotide targeted to a site to induce exon skipping, classifiable in class 514, subclass 44. This group is subject to a further restriction of an exon and corresponding antisense molecule.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the antisense

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molecule can be used in a materially different process such as in *in situ hybridization*. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement

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may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Furthermore, should applicants elect to prosecute groups I or II, these groups are subject to further restriction as follows. Claims 1, 2 and 15 are subject to an additional restriction since it is not considered to be a proper genus/Markush. See MPEP 803.02 – PRACTICE RE MARKUSH-TYPE CLAIMS – if the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claims on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 300 (CCPA 1980); and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. In *re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structure feature disclosed as being essential to that utility.

Claims 1, 2 and 15 specifically claim groups of antisense oligonucleotides that target exons 3, 4, 8, 10 to 16, 19 to 40, 42 to 44, 46, 47, and 50 to 53. For example, antisense oligonucleotides targeting exon 3 are represented as SEQ ID Nos. 23-30 as shown in Table on page 11 of the instant specification. Each group of antisense sequences targeting different exons are considered to be unrelated as each is

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structurally and functionally independent and distinct. Each group of antisense sequences target and modulate different exons.

Furthermore, a search of more than one (1) of the groups of exons targeting different exons claimed in claims 1, 2 and 15 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the exons and corresponding antisense sequences. In view of the foregoing, one (1) exon and antisense sequence are considered to be a reasonable number of sequences for examination. Accordingly, applicants are required to elect a total of one (1) exon and antisense sequence from claims 1, 2 and 15. **Note the election of one exon and corresponding antisense sequences are not a species election.**

This application contains claims directed to the following patentably distinct species.

Applicant is required to elect an exon above and corresponding antisense sequences from SEQ ID Nos. 1-202 and Sequences of claim 15 and from that election, the group of antisense sequences are subject to a further species election below.

Claims 1, 2 and 15 are directed to patentably distinct antisense sequences. For example, SEQ ID Nos. 23-30 each target exon 3 and are patentably distinct. . The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not

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obvious variants of each other based on the current record and a search for one sequence would not necessarily reveal art against any other sequence.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the

Application/Control Number: 13/963,578
Art Unit: 1635

Page 8

requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double

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patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Kimberly Chong whose telephone number is 571-272-3111**. The examiner can normally be reached Monday thru Friday between 9-5 pm.

If attempts to reach the examiner by telephone are unsuccessful please contact the Acting SPE for 1635 Heather Calamita at 571-272-2876. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Kimberly Chong/
Primary Examiner
Art Unit 1635



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/086,859	11/21/2013	Stephen Donald Wilton	AVN-008CN19 / TRACK1	9542
123147	7590	06/30/2014	EXAMINER	
Nelson Mullins Riley & Scarborough LLP/Sarepta One Post Office Square Boston, MA 02109			CHONG, KIMBERLY	
			ART UNIT	PAPER NUMBER
			1674	
			NOTIFICATION DATE	DELIVERY MODE
			06/30/2014	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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ipqualityassuranceboston@nelsonmullins.com

Office Action SummaryApplication No.
14/086,859Applicant(s)
WILTON ET AL.Examiner
KIMBERLY CHONGArt Unit
1674AIA (First Inventor to File)
Status
No**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04/28/2014.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 21-49 is/are pending in the application.
5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 21-49 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date 04/28/2014.
- 3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 4) ☐ Other: ____.

Application/Control Number: 14/086,859
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Page 2

The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed 04/28/2014 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 01/27/2014 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

With entry of the amendment filed on 04/28/2014, claims 21-49 are pending and currently under examination.

Information Disclosure Statement

The submission of the Information Disclosure Statement on 04/28/2014 is in compliance with 37 CFR 1.97. The information disclosure statement has been considered by the examiner and signed copies have been placed in the file.

Claim Rejections - 35 USC § 103

The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which

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said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-49 are rejected under pre-AIA 35 U.S.C. 103(a) as being obvious over van Ommen (US Application 20060147952 cited on IDS filed 12/19/2013), Baker et al. (US Application 20050048495), Matteucci, M. (Perspectives in Drug Disc. and Design, 1996, vol. 4, pp 1-16 cited on IDS filed 12/19/2013) and Matsuo et al. (US 6,653,467 cited on IDS filed 12/19/2013).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under pre-AIA 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The claims are drawn to an isolated antisense oligonucleotide of 20-50 nucleotides comprising at least 20 bases of SEQ ID No. 193, wherein at least one pyrimidine base of the oligonucleotide comprises a 5-substituted pyrimidine base or at least one purine base comprises an N-2, N-6 substituted purine base and uracil bases are optionally thymine based, wherein the oligonucleotide comprises a modification to minimize or prevent cleavage by RNase H, wherein said oligonucleotide induces exon 53 skipping and a composition comprising said antisense oligonucleotide.

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van Ommen teach an oligonucleotide having SEQ ID No. 29 that has 18 nucleotides identical to the claimed SEQ ID No. 193. van Ommen teach the oligonucleotide can comprise modified nucleotides such as 2'-O-methyl, a morpholine ring, peptide nucleic acids and locked nucleic acids (see paragraph 0019).

van Ommen teach in [0018] oligonucleotides that are complementary to a consecutive part of between 16 and 50 nucleotides of an exon RNA and teach different types of nucleic acid molecules can be used to generate the oligonucleotide.

[0018] The complementary oligonucleotide generated through a method of the invention is preferably complementary to a consecutive part of between 16 and 50 nucleotides of the exon RNA. Different types of nucleic acid may be used to generate the oligonucleotide.

van Ommen teach in [0015] and [0016] the use of oligonucleotides to skip exons such as exon 53. In paragraph [0019] it is taught that the oligonucleotide can have modifications such as morpholino phosphorodiamidate, peptide nucleic acid and locked nucleic acids, for example, and further teach the oligonucleotide comprises modified internucleoside linkages.

[0019] With the advent of nucleic acid-mimicking technology, it has become possible to generate molecules that have a similar, preferably the same, hybridization characteristics, in kind, not necessarily in amount, as nucleic acid itself. Such equivalents are, of course, also part of the invention. Examples of such mimics equivalents are peptide nucleic acid, locked nucleic acid and/or a morpholino phosphorodiamidate...Hybrids between one or more of the equivalents among each other and/or together with nucleic acid are, of course, also part of the invention. In a preferred embodiment, an equivalent comprises locked nucleic acid, as locked nucleic acid displays a higher target affinity and reduced toxicity and, therefore, shows a higher efficiency of exon skipping.

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van Ommen et al. do not specifically teach an oligonucleotide comprising a 5-substituted pyrimidine base, an N-2, N-6 substituted purine base or conjugates as claimed.

Baker et al. teach antisense oligonucleotide molecules comprising modified pyrimidine or purine bases as claimed and teach such modifications are particularly useful at increasing the binding affinity of the oligonucleotides (see 0091). Baker et al. further teach conjugates such as polyamine or polyethylene glycol chemically linked to the antisense oligonucleotide enhance the activity, cellular distribution and cellular uptake of the oligonucleotides (see 0094).

It would have been obvious for one of ordinary skill in the art to incorporate the modifications taught by Baker et al. into the oligonucleotide taught by van Ommen. Based on the advantages taught by Baker et al. such as increased binding affinity and enhanced activity, cellular distribution and cellular uptake of the oligonucleotides, one of ordinary skill in the art would have clearly been motivated and would have expected to be capable of making a molecule with these modifications.

With respect to the claimed oligonucleotide comprising at least 20 bases of SEQ ID No. 193, van Ommen teach a genus of oligonucleotides targeted to exon 53 wherein the oligonucleotides are complementary to a consecutive part of between 16 and 50 nucleotides of an exon 53 (see 0018) and therefore teach antisense oligonucleotides of 16 to 50 nucleotides in length. MPEP 2131.02 states that if one of ordinary skill in the art is able to "at once envisage" the specific compound within a genus, the compound is anticipated.

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2131.02 Genus-Species Situations [R-11.2013]

III. A GENERIC DISCLOSURE WILL ANTICIPATE A CLAIMED SPECIES COVERED BY THAT DISCLOSURE WHEN THE SPECIES CAN BE “AT ONCE ENVISAGED” FROM THE DISCLOSURE

“[W]hether a generic disclosure necessarily anticipates everything within the genus ... depends on the factual aspects of the specific disclosure and the particular products at issue.” *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1083, 89 USPQ2d 1370, 1375 (Fed. Cir. 2008). See also *Osram Sylvania Inc. v. American Induction Tech.*, 701 F.3d 698, 706, 105 USPQ2d 1368, 1374 (Fed. Cir. 2012) (“how one of ordinary skill in the art would understand the relative size of a genus or species in a particular technology is of critical importance”).

For example, when a claimed compound is not specifically named in a reference, but instead it is necessary to select portions of teachings within the reference and combine them, e.g., select various substituents from a list of alternatives given for placement at specific sites on a generic chemical formula to arrive at a specific composition, anticipation can only be found if the classes of substituents are sufficiently limited or well delineated. *Ex parte A*, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990). If one of ordinary skill in the art is able to “at once envisage” the specific compound within the generic chemical formula, the compound is anticipated. One of ordinary skill in the art must be able to draw the structural formula or write the name of each of the compounds included in the generic formula before any of the compounds can be “at once envisaged.” One may look to the preferred embodiments to determine which compounds can be anticipated. *In re Petering*, 301 F.2d 676, 133 USPQ 275 (CCPA 1962).

Given that van Ommen et al. teach oligonucleotides of 16 to 50 nucleotides in length that are complementary to exon 53 and the sequence of exon 53 is known in the prior art and further teach an oligonucleotide having 18 identical nucleotides of the claimed SEQ ID No. 193, one of ordinary skill in the art is clearly able to envisage an oligonucleotide of at least 20 nucleotides, 2 nucleotides longer than taught by van Ommen et al., that is complementary to exon 53. One would have been motivated to make any oligonucleotide of 16 to 50 nucleotides targeted to the known specific target region of exon 53 wherein van Ommen et al. demonstrates exon skipping. As

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evidenced by Matsuo et al., it was known in the prior art that antisense oligonucleotides longer than 18 nucleotides in length were capable of inducing exon skipping (see columns 10 and 11).

With respect to the claimed antisense oligonucleotide optionally comprising uracil bases, Table 1A in the instant specification teach substitution of a U by a T would be using other antisense chemistries such as peptide nucleic acids or morpholinos “(TABLE-US-00001 [0051] TABLE 1A Description of 2'-O-methyl phosphorothioate antisense oligonucleotides that have been used to date to study induced exon skipping during the processing of the dystrophin pre-mRNA. Since these 2'-O-methyl antisense oligonucleotides are more RNA-like, U represents uracil. With other antisense chemistries such as peptide nucleic acids or morpholinos, these U bases may be shown as "T")”. Given van Ommen et al. teach that the oligonucleotide can comprise different types of nucleic acids (which would be DNA or RNA) and teach modifications such as peptide nucleic acids or morpholinos, it would be obvious for van Ommen et al. to incorporate such a modification and thus van Ommen et al. essentially teach an oligonucleotide wherein uracil bases are optionally thymine bases.

Moreover, it is well known in the art that antisense oligonucleotides comprising thymine bases enhance the affinity of the oligonucleotides to the target sequence as compared to uracil bases (see Matteucci at page 10). It would have been further obvious for one of ordinary skill in the art to substitute thymine bases for the uracil bases in the antisense oligonucleotide taught by van Ommen et al. One of skill in the art would have wanted to maximize the binding affinity of the antisense oligonucleotide

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to the target exon for more efficient exon skipping and would have therefore incorporated thymine bases in place of uracil bases for increased affinity as taught by Matteucci. One of ordinary skill in the art would have expected to be capable of making this base substitution, the steps of which are routine to the skilled artisan.

Thus in the absence of evidence to the contrary, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21-49 are provisionally rejected under the judicially created doctrine of double patenting over claim 1 of copending Application No. 14/273,379. This is a provisional double patenting rejection since the conflicting claims have not yet been patented. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of the patent are drawn to patently indistinguishable subject matter.

Application/Control Number: 14/086,859
Art Unit: 1674

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Kimberly Chong** whose telephone number is **571-272-3111**. The examiner can normally be reached Monday thru Friday between 9-5 pm.

If attempts to reach the examiner by telephone are unsuccessful please contact the SPE for 1674 Christopher Babic at 571-272-8507. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Kimberly Chong/
Primary Examiner
Art Unit 1674



UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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14/086,859

11/21/2013

Stephen Donald Wilton

AVN-008CN19

9542

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7590

01/27/2014

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EXAMINER

CHONG, KIMBERLY

ART UNIT

PAPER NUMBER

1674

MAIL DATE

DELIVERY MODE

01/27/2014

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action SummaryApplication No.
14/086,859Applicant(s)
WILTON ET AL.Examiner
KIMBERLY CHONGArt Unit
1674AIA (First Inventor to File)
Status
No**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/19/2013.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 21-49 is/are pending in the application.
 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 21-49 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 11/21/2013 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
 Paper No(s)/Mail Date 12/19/2013.
- 3) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. ____.
- 4) ☐ Other: ____.

Application/Control Number: 14/086,859
Art Unit: 1674

Page 2

The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

Status of the Application

Claims 21-49 are pending and are currently under examination. Claims 21-49 are free of the prior art searched with respect to SEQ ID No. 193.

Information Disclosure Statement

The submission of the Information Disclosure Statement on 12/19/2013 is in compliance with 37 CFR 1.97. The information disclosure statement has been considered by the examiner and signed copies have been placed in the file.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Art Unit: 1674

Page 3

Claims 21-49 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36 of U.S. Patent No. 8,455,636. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of the patent are drawn to patently indistinguishable subject matter as they are both drawn to antisense oligonucleotide targeted to an exon 53 target region.

Claims 21-49 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 8,232,384. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of the patent are drawn to patently indistinguishable subject matter as they are both drawn to antisense oligonucleotide targeted to an exon 53 target region.

Claims 21-49 are provisionally rejected under the judicially created doctrine of double patenting over claims 2 and 3 of copending Application No. 13/902,376. This is a provisional double patenting rejection since the conflicting claims have not yet been patented. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of the patent are drawn to patently indistinguishable subject matter as they are both drawn to antisense oligonucleotide targeted to an exon 53 target region.

Application/Control Number: 14/086,859
Art Unit: 1674

Page 4

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Kimberly Chong** whose telephone number is **571-272-3111**. The examiner can normally be reached Monday thru Friday between 9-5 pm.

If attempts to reach the examiner by telephone are unsuccessful please contact the SPE for 1674 Christopher Babic at 571-272-8507. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Kimberly Chong/
Primary Examiner
Art Unit 1674



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/108,137	12/16/2013	Stephen Donald Wilton	AVN-015USCN	7024

123147 7590 04/29/2015
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

EXAMINER

VIVLEMORE, TRACY ANN

ART UNIT	PAPER NUMBER
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1674

NOTIFICATION DATE	DELIVERY MODE
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04/29/2015

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipboston.docketing@nelsonmullins.com
chris.schlauch@nelsonmullins.com
ipqualityassuranceboston@nelsonmullins.com

Office Action SummaryApplication No.
14/108,137Applicant(s)
WILTON ET AL.Examiner
Tracy VivlemoreArt Unit
1674AIA (First Inventor to File)
Status
No**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/3/15.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 1 and 4-12 is/are pending in the application.
5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1 and 4-12 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date 12 documents.
- 3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 4) ☐ Other: ____.

Application/Control Number: 14/108,137
Art Unit: 1674

Page 2

DETAILED ACTION

The present application is being examined under the pre-AIA first to invent provisions.

Election/Restrictions

Applicant's election of the nucleotide sequences listed in the reply filed on April 3, 2015 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*,

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686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit <http://www.uspto.gov/forms/>. The filing date of the application will determine what form should be used. **A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to <http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp>.**

Claims 1 and 4-12 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1, 11, 12, 15, 16, 20, 22, 47, 53, 54, 57, 58, 62, 64, 65 and 67 of U.S. Patent No. 8,524,880. Although the claims at issue are not identical, they are not patentably distinct from each other because the patent claims are directed to SEQ ID NO: 207, which in some embodiments comprise morpholinos and may be conjugated to a moiety such as polyethylene glycol. This sequence comprises instant

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SEQ ID NO: 63 and thus the patent claims are directed to a species that would anticipate the instant claims.

Applicant is advised that should claim 1 and 9 be found allowable, claims 4, 5, 10 and 11 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). While claim 4 does not specifically recite SEQ ID NOs, the subject matter of this claim is identical to that of claim 1; each of subsections (i)-(xx) of claim 4 describe a sequence that corresponds to the sequences recited in claim 1. For example, claim 1 recites a morpholino antisense of SEQ ID NO: 11 with optional modifications, which is a 34 nucleotide sequence that is 100% complementary to the annealing site H45A (-09+25) recited in subsection (i) of claim 4.

Claim Rejections - 35 USC § 112

The following is a quotation of 35 U.S.C. 112(d):

(d) REFERENCE IN DEPENDENT FORMS.—Subject to subsection (e), a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), fourth paragraph:

Subject to the [fifth paragraph of 35 U.S.C. 112 (pre-AIA)], a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

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Claim 5 is rejected under 35 U.S.C. 112(d) or pre-AIA 35 U.S.C. 112, 4th paragraph, as being of improper dependent form for failing to further limit the subject matter of the claim upon which it depends, or for failing to include all the limitations of the claim upon which it depends. Claim 5 depends from claim 4 and recites specific SEQ ID NOs which correspond exactly to the sequences recited in word form in claim 4. Applicant may cancel the claim(s), amend the claim(s) to place the claim(s) in proper dependent form, rewrite the claim(s) in independent form, or present a sufficient showing that the dependent claim(s) complies with the statutory requirements.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of pre-AIA 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 4-12 are rejected under pre-AIA 35 U.S.C. 102(e) as being anticipated by Sazani et al. (US 2010/0130591, cited on IDS).

Sazani et al. disclose antisense molecules capable of binding to a selected target site in the human dystrophin gene to induce exon skipping, and methods of use thereof to treat muscular dystrophy (see abstract). At paragraphs 97-98 Sazani et al. disclose the antisense oligonucleotide compounds of their invention comprise morpholino

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subunits and phosphorus-containing intersubunit linkages joining a morpholino nitrogen of one subunit to a 5' exocyclic carbon of an adjacent subunit. The oligomer may comprise modified bases such as 5-substituted pyrimidines, 6-azapyrimidines and 2-substituted purines. Sazani et al. further note persons skilled in the art will appreciate that Ts and Us are interchangeable and T bases may be shown as U as for example, in the sequence listing. Sazani et al. further disclose at paragraph 46 that the oligomer may be conjugated to a moiety that enhances the solubility of the oligomer in aqueous medium, such as polyethylene glycol. Conjugation of the moiety that enhances solubility of the oligomer in aqueous medium to the oligomer may be either directly or through a linker moiety. Sequences disclosed by Sazani et al. are shown starting at page 25 and include SEQ ID NOs: 29, 613 and 28, which comprise instant SEQ ID NOs: 63, 64 and 65, respectively.

Allowable Subject Matter

SEQ ID NOs: 11, 55, 66, 239, 240, 244 and 245 are free of the prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya, can be reached on 571-272-0806. The central FAX Number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tracy Vivlemore
Primary Examiner
Art Unit 1674

/Tracy Vivlemore/
Primary Examiner, Art Unit 1674



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/108,137	12/16/2013	Stephen Donald Wilton	AVN-015USCN	7024
123147	7590	10/03/2014		
Nelson Mullins Riley & Scarborough LLP/Sarepta One Post Office Square Boston, MA 02109			EXAMINER VIVLEMORE, TRACY ANN	
			ART UNIT	PAPER NUMBER
			1674	
			NOTIFICATION DATE	DELIVERY MODE
			10/03/2014	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipboston.docketing@nelsonmullins.com
chris.schlauch@nelsonmullins.com
ipqualityassuranceboston@nelsonmullins.com

Application No.
14/108,137
#: 58099Applicant(s)
WILTON ET AL.**Office Action Summary**Examiner
Tracy VivlemoreArt Unit
1674AIA (First Inventor to File)
Status
No**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/6/14.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 1-3 is/are pending in the application.
 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☐ Claim(s) ____ is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☒ Claim(s) 1-3 are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
 Paper No(s)/Mail Date ____.
- 3) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date ____.
- 4) ☐ Other: ____.

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DETAILED ACTION

The present application is being examined under the pre-AIA first to invent provisions.

Election/Restrictions

This application contains claims directed to the following patentably distinct species of the antisense sequences recited in claim 1. The species are independent or distinct because each has a unique nucleotide sequence. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect up to 10 nucleotide sequences, or a single grouping of patentably indistinct species, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

There is a search and/or examination burden for the patentably distinct species as set forth above because at least the following reason(s) apply: the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species or grouping of patentably indistinct species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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The election may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species or grouping of patentably indistinct species.

Should applicant traverse on the ground that the species, or groupings of patentably indistinct species from which election is required, are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing them to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 or pre-AIA 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be corrected in compliance with 37 CFR 1.48(a) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. A request to correct inventorship under 37 CFR 1.48(a) must be accompanied by an application data sheet in accordance with 37 CFR 1.76 that

Application/Control Number: 14/108,137
Art Unit: 1674

Page 4

identifies each inventor by his or her legal name and by the processing fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is (571)272-2914. The examiner can normally be reached on Mon-Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Babic can be reached on 571-272-8507. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tracy Vivlemore
Primary Examiner
Art Unit 1674

/Tracy Vivlemore/
Primary Examiner, Art Unit 1674



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

123147 7590 10/09/2015
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

EXAMINER	
VIVLEMORE, TRACY ANN	
ART UNIT	PAPER NUMBER
1674	

DATE MAILED: 10/09/2015

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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14/108,137 12/16/2013 Stephen Donald Wilton AVN-015USCN 7024

TITLE OF INVENTION: ANTISENSE MOLECULES AND METHODS FOR TREATING PATHOLOGIES

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$480	\$0	\$0	\$480	01/11/2016

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL
#: 36104

Complete and send this form, together with applicable fee(s), to: **Mail** **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

123147 7590 10/09/2015
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

14/108,137

12/16/2013

Stephen Donald Wilton

AVN-015USCN

7024

TITLE OF INVENTION: ANTISENSE MOLECULES AND METHODS FOR TREATING PATHOLOGIES

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
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nonprovisional

SMALL

\$480

\$0

\$0

\$480

01/11/2016

EXAMINER	ART UNIT	CLASS-SUBCLASS
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VIVLEMORE, TRACY ANN

1674

514-04400A

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

1 _____

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

☐ Issue Fee☐ Publication Fee (No small entity discount permitted)☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

☐ A check is enclosed.☐ Payment by credit card. Form PTO-2038 is attached.

☐ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29☐ Applicant asserting small entity status. See 37 CFR 1.27☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



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United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/108,137	12/16/2013	Stephen Donald Wilton	AVN-015USCN	7024

EXAMINER
VIVLEMORE, TRACY ANN

ART UNIT	PAPER NUMBER
1674	

123147 7590 10/09/2015
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

DATE MAILED: 10/09/2015

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 14/108,137 Examiner Tracy Vivlemore	Applicant(s) WILTON ET AL. Art Unit 1674 AIA (First Inventor to File) Status No
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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the reply filed 8/4/15.
☐ A declaration(s)/affidavit(s) under 37 CFR 1.130(b) was/were filed on ____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are 4,6-8 and 13-86. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/oph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
Certified copies:
 a) ☒ All b) ☐ Some *c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 13/509,331.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 * Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date <u>7 documents</u> 3. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material 4. <input type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date ____ .	5. <input type="checkbox"/> Examiner's Amendment/Comment 6. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance 7. <input type="checkbox"/> Other _____.
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	/Tracy Vivlemore/ Primary Examiner, Art Unit 1674
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United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/178,059	02/11/2014	Stephen Donald WILTON	AVN-008CN20	5831

959 7590 03/31/2014
NELSON MULLINS RILEY & SCARBOROUGH LLP
FLOOR 30, SUITE 3000
ONE POST OFFICE SQUARE
BOSTON, MA 02109

EXAMINER

CHONG, KIMBERLY

ART UNIT	PAPER NUMBER
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1674

MAIL DATE	DELIVERY MODE
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03/31/2014

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No.
14/178,059
#: 58109Applicant(s)
WILTON ET AL.**Office Action Summary**Examiner
KIMBERLY CHONGArt Unit
1674AIA (First Inventor to File)
Status
No**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03/20/2014.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 2-7 is/are pending in the application.
 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 2-7 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 02/11/2014 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
 Paper No(s)/Mail Date 03/20/2014.
- 3) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. ____.
- 4) ☐ Other: ____.

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The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

Status of the Application

Claims 2-7 are pending and are currently under examination.

Information Disclosure Statement

The submission of the Information Disclosure Statement on 03/20/2014 is in compliance with 37 CFR 1.97. The information disclosure statement has been considered by the examiner and signed copies have been placed in the file.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of pre-AIA 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 2-7 are rejected under pre-AIA 35 U.S.C. 102(e) as being anticipated by van Deutekom (US Application 20130072671 cited on IDS filed 03/20/2014).

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Art Unit: 1674

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The claims are drawn to an isolated antisense oligonucleotide of 20 to 50 nucleotides in length complementary to exon 51 of the human dystrophin pre-mRNA wherein said target sequence comprises a nucleotide sequence that is complementary to the sequence having SEQ ID No. 180, wherein said oligonucleotide comprises a morpholine ring, a peptide nucleic acid or a locked nucleic acid or comprises a 2'-O-methyl ribose moiety.

The claims are interpreted as the antisense oligonucleotide comprises a nucleotide sequence having at least 20 nucleotides of the sequence TGT AGT TCC TTC TAC CGT AAA GAT C, which is a nucleotide sequence that is complementary to the sequence having SEQ ID No. 180.

van Deutekom teach in [0020] oligonucleotides that are complementary to a consecutive part of between 16 and 50 nucleotides of an exon RNA and teach different types of nucleic acid molecules can be used to generate the oligonucleotide.

[0020] The complementary oligonucleotide generated through a method of the invention is preferably complementary to a consecutive part of between 16 and 50 nucleotides of the exon RNA. Different types of nucleic acid may be used to generate the oligonucleotide.

van Deutekom teach in [0018 and 0019] the use of oligonucleotides to skip exons such as exon 51. In paragraphs [0020 and 0021] it is taught that the oligonucleotide can have modifications such as morpholino phosphorodiamidate, peptide nucleic acid and locked nucleic acids, for example, and further teach the oligonucleotide comprises modified internucleoside linkages.

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[0021] With the advent of nucleic acid-mimicking technology, it has become possible to generate molecules that have a similar, preferably the same, hybridization characteristics, in kind, not necessarily in amount, as nucleic acid itself. Such equivalents are, of course, also part of the invention. Examples of such mimics equivalents are peptide nucleic acid, locked nucleic acid and/or a morpholino phosphorodiamidate...Hybrids between one or more of the equivalents among each other and/or together with nucleic acid are, of course, also part of the invention. In a preferred embodiment, an equivalent comprises locked nucleic acid, as locked nucleic acid displays a higher target affinity and reduced toxicity and, therefore, shows a higher efficiency of exon skipping.

van Deutekom teach in [0020] that the oligonucleotide preferably comprises RNA, which would mean that the oligonucleotide is also DNA. Thus while van Deutekom teach a preferred embodiment of RNA oligonucleotides, DNA oligonucleotides are also taught and finds support on page 10 of the specification which discusses examples of DNA oligonucleotides known in the prior art e.g. oligonucleotides containing locked nucleic acids (DNA analogs).

MPEP 2123 states in part:

A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also > *Upsher-Smith Labs. v. Pamlab, LLC*, 412 F.3d 1319, 1323, 75 USPQ2d 1213, 1215 (Fed. Cir. 2005)(reference disclosing optional inclusion of a particular component teaches compositions that both do and do not contain that component); < *Celeritas Technologies Ltd. v. Rockwell International Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998) (The court held that the prior art anticipated the claims even though it taught away from the claimed invention. "The fact that a modem with a single carrier data signal is shown to be less than optimal does not vitiate the fact that it is disclosed."). {emphasis added}

Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994) (The invention was directed to an epoxy impregnated fiber-reinforced printed circuit material. The applied prior art reference taught a printed circuit material similar to that of the claims but impregnated with polyester-imide resin instead of epoxy. The reference, however, disclosed that epoxy was known for this use,

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but that epoxy impregnated circuit boards have "relatively acceptable dimensional stability" and "some degree of flexibility," but are inferior to circuit boards impregnated with polyester-imide resins. The court upheld the rejection concluding that applicant's argument that the reference teaches away from using epoxy was insufficient to overcome the rejection since "Gurley asserted no discovery beyond what was known in the art." 27 F.3d at 554, 31 USPQ2d at 1132.). Furthermore, "[t]he prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed...." In re Fulton, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004). {emphasis added}.

van Deutekom reasonably teach to one having ordinary skill in the art nonpreferred embodiments of DNA oligonucleotides and that are complementary to a target sequence of exon 51, wherein the target sequence would comprise a 20 nucleotide part that is complementary to the oligonucleotide having SEQ ID No. 27.

Thus van Deutekom anticipates the instant claims.

Applicant has provided a detailed argument of why van Deutekom is not prior art in anticipation of this reference being cited and thus in the interest of compact prosecution, the arguments will be addressed.

Applicant states van Deutekom and the claim amendments filed 01/21/2014 (which have been duplicated in the instant application) lack proper written description and thus is unsupported by the priority documents and is not prior art. Applicant argues van Deutekom were only in possession of RNA oligonucleotides and not DNA oligonucleotides. As explained above van Deutekom reasonably teach to one having ordinary skill in the art nonpreferred embodiments of DNA oligonucleotides.

Applicants argue oligonucleotides had an established meaning to those of ordinary skill in the art as of the date of the invention of the van Deutekom application

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and as shown by Gerwitz (cited in the remarks filed 03/20/2014), which provides evidence that those of ordinary skill in the relevant art understood the term oligonucleotide encompasses both DNA and RNA oligonucleotides, further teach RNA and DNA oligonucleotides had different advantages and disadvantages and one of ordinary skill would understand that Gerwitz teach RNA oligonucleotides would be appropriate for exon skipping.

This argument is not persuasive to ignore what the term "oligonucleotide" would mean to one of ordinary skill in the art. Gerwitz provides sufficient evidence, as acknowledged by Applicant, that one of ordinary skill in the relevant art would understand that oligonucleotide encompasses both RNA and DNA oligonucleotides. Thus with Gerwitz providing evidence that one would understand that an oligonucleotide encompasses both RNA and DNA oligonucleotides, van Deutekom clearly teach DNA oligonucleotides.

Applicant further argues that the term complementary is not defined in the van Deutekom specification to support the claimed invention because the term is defined to include mismatches. Again while van Deutekom does state the complementary oligonucleotide can have mismatches to the target sequence, this is a preferred embodiment and the specification as a whole does not teach away from a complementary oligonucleotide targeted to exon 51 and one of skill in the art can readily identify complementary oligonucleotides to exon 51, wherein the target sequence would comprise a 20 nucleotide part that is complementary to the oligonucleotide having SEQ ID No. 27.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Kimberly Chong** whose telephone number is **571-272-3111**. The examiner can normally be reached Monday thru Friday between 9-5 pm.

If attempts to reach the examiner by telephone are unsuccessful please contact the SPE for 1674 Christopher Babic at 571-272-8507. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Kimberly Chong/
Primary Examiner
Art Unit 1674



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NOTICE OF ALLOWANCE AND FEE(S) DUE

959 7590 09/15/2015
NELSON MULLINS RILEY & SCARBOROUGH LLP
FLOOR 30, SUITE 3000
ONE POST OFFICE SQUARE
BOSTON, MA 02109

EXAMINER	
SHIN, DANA H	
ART UNIT	PAPER NUMBER
1674	

DATE MAILED: 09/15/2015

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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14/213,607 03/14/2014 Richard K. BESTWICK AVN-013A 1039

TITLE OF INVENTION: EXON SKIPPING COMPOSITIONS FOR TREATING MUSCULAR DYSTROPHY

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$480	\$0	\$0	\$480	12/15/2015

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL
#: 36117

Complete and send this form, together with applicable fee(s), to: **Mail** **Mail Stop ISSUE FEE**
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

959 7590 09/15/2015
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Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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14/213,607

03/14/2014

Richard K. BESTWICK

AVN-013A

1039

TITLE OF INVENTION: EXON SKIPPING COMPOSITIONS FOR TREATING MUSCULAR DYSTROPHY

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
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nonprovisional

SMALL

\$480

\$0

\$0

\$480

12/15/2015

EXAMINER	ART UNIT	CLASS-SUBCLASS
----------	----------	----------------

SHIN, DANA H

1674

514-04400A

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

1 _____

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

☐ Issue Fee☐ Publication Fee (No small entity discount permitted)☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

☐ A check is enclosed.☐ Payment by credit card. Form PTO-2038 is attached.

☐ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29☐ Applicant asserting small entity status. See 37 CFR 1.27☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/213,607	03/14/2014	Richard K. BESTWICK	AVN-013A	1039

EXAMINER
SHIN, DANA H

ART UNIT	PAPER NUMBER
1674	

DATE MAILED: 09/15/2015

959 7590 09/15/2015
NELSON MULLINS RILEY & SCARBOROUGH LLP
FLOOR 30, SUITE 3000
ONE POST OFFICE SQUARE
BOSTON, MA 02109

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

36119

<i>Notice Requiring Inventor's Oath or Declaration</i>	Application No. 14/213,607	Applicant(s) Richard K. BESTWICK	
	Examiner SHIN, DANA H	Art Unit 1674	

This notice is an attachment to the Notice of Allowability (PTOL-37), or the Notice of Allowability For A Design Application (PTOL-37D).

An inventor's oath or declaration in compliance with 37 CFR 1.63 or 1.64 executed by or with respect to each inventor has not yet been submitted.

An oath or declaration in compliance with 37 CFR 1.63, or a substitute statement in compliance with 37 CFR 1.64, executed by or with respect to each inventor (for any inventor for which a compliant oath, declaration, or substitute statement has not yet been submitted) **MUST** be filed no later than the date on which the issue fee is paid. See 35 U.S.C. 115(f). Failure to timely comply will result in ABANDONMENT of this application.

A properly executed inventor's oath to declaration has not been received for the following inventor(s):

If applicant previously filed one or more oaths, declarations, or substitute statements, applicant may have received an informational notice regarding deficiencies therein.

The following deficiencies are noted:

INFORMAL ACTION PROBLEMS

- A properly executed inventor's oath or declaration has not been received for the following inventor(s):
Richard K. BESTWICK and Diane Elizabeth FRANK.
Applicant may submit the inventor's oath or declaration at any time before the Notice of Allowance and Fee(s) Due, PTOL-85, is mailed.

Questions relating to this Notice should be directed to the Application Assistance Unit at 571-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 14/213,607	Applicant(s) BESTWICK ET AL.	
	Examiner DANA SHIN	Art Unit 1674	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to claim amendments filed on 9-1-2015.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are 60-65. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a) ☐ All b) ☐ Some *c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

<ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____ 3. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material 4. <input type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date _____ 	<ol style="list-style-type: none"> 5. <input type="checkbox"/> Examiner's Amendment/Comment 6. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance 7. <input type="checkbox"/> Other _____
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/DANA SHIN/ Primary Examiner, Art Unit 1674	
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/213,607	03/14/2014	Richard K. BESTWICK	AVN-013A	1039

959 7590 04/01/2015
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EXAMINER

SHIN, DANA H

ART UNIT	PAPER NUMBER
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1674

NOTIFICATION DATE	DELIVERY MODE
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04/01/2015

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipboston.docketing@nelsonmullins.com
chris.schlauch@nelsonmullins.com
ipqualityassuranceboston@nelsonmullins.com

Application No.
14/213,607
58123Applicant(s)
BESTWICK ET AL.**Office Action Summary**Examiner
DANA SHINArt Unit
1674AIA (First Inventor to File)
Status
No**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3-18-2015.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 1-3,15-20,32-37 and 41-65 is/are pending in the application.
 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☒ Claim(s) 60-65 is/are allowed.
- 7) ☒ Claim(s) 1,2,15-20,32-37 and 41-59 is/are rejected.
- 8) ☒ Claim(s) 3 is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 3-14-2014 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
 Paper No(s)/Mail Date ____.
- 3) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date ____.
- 4) ☐ Other: ____.

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DETAILED ACTION

The present application is being examined under the pre-AIA first to invent provisions.

Election/Restrictions

Applicant's election without traverse of claims 1-38 and 41-42 with species election of SEQ ID NO:6 in the reply filed on March 18, 2015 is acknowledged.

Status of Claims

Claims 1-3, 15-20, 32-37, and 41-65 are pending and under examination on the merits in the instant application.

Information Disclosure Statement

The information disclosure statements submitted on March 18, 2015 have been considered by the examiner, except the information pertaining to AU 2003284638 A1 since applicant did not submit legible copies of the reference. Note that applicant merely submitted the cover page only. Further, JP2008507577 is not considered because the entire reference is in non-English language. In addition, non-English language references such as JP 2000-325085, JP2014138589, WO 2004/048570, WO 2006/021724, and WO 2013/100190 are considered only insofar as the English title and abstract.

Claim Rejections - 35 USC § 112

The following is a quotation of 35 U.S.C. 112(b):

(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

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The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-20, 32-37, 41-42, 49-53, and 57-59 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

The claims recite target regions in terms of which appears to be nucleotide positions. The recitation of target regions by nucleotide positions without specifically pointing out the target SEQ ID NO renders the claims indefinite because the nucleotide positions are not unchanging, definitive information as nucleotide sequences are constantly updated and there are nucleotide sequence variations.

For examination purpose, the recited regions will be interpreted as the nucleotide sequences targeted by SEQ ID NOs:4-7 in view of the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of pre-AIA 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the

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international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 15-20, 32-34, 41, 43-47, 49-52, and 54-59 are rejected under pre-AIA 35 U.S.C. 102(a) and 102(e) as being anticipated by Hanson et al. (US 2012/0065169 A1).

Hanson et al. disclose a 25-mer morpholino antisense oligonucleotide comprising SEQ ID NO:23, which comprises at least 17 consecutive bases of SEQ ID NO:6 claimed in the instant case.

Hanson et al. teach that the oligonucleotide comprises 5-methyl cytosine. See paragraph 0289.

Hanson et al. teach that the oligonucleotide comprises a cell-penetrating peptide such as an arginine-rich peptide or chemically linked to triethyleneglycolyl (EG3). See paragraphs 0265, 0269.

Hanson et al. teach that the oligonucleotide is formulated as a pharmaceutical composition comprising a pharmaceutically acceptable vehicle. See paragraph 0305.

Accordingly, all claim limitations are taught by Hanson et al.

Claims 1, 15-20, 32-37, 41, 43-45, 49-50, and 54-59 are rejected under pre-AIA 35 U.S.C. 102(a) and 102(e) as being anticipated by Popplewell et al. (US 2012/0065244 A1).

Popplewell et al. disclose a 30-mer PMO antisense oligonucleotide SEQ ID NO:15, which comprises at least 17 consecutive nucleotides of SEQ ID NO:6 claimed in the instant case.

Popplewell et al. teach that the oligonucleotide of SEQ ID NO:3 (corresponding to SEQ ID NO:15) can be 25, 26, 27, 28, 29, and 30 nucleotides in length, wherein X is T or U. See paragraphs 0011, 0027.

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Popplewell et al. teach that the oligonucleotide is formulated as a pharmaceutical composition comprising pharmaceutically acceptable carrier or polyethylene glycol or “an arginine-rich cell penetrating peptide (CPP)” or an expression vector such as “an adeno-associated virus (AVV) vector”. See paragraphs 0032-0035.

Accordingly, all claim limitations are taught by Popplewell et al.

Claims 1-2, 15, 17-20, 32, 34-35, and 41-59 are rejected under pre-AIA 35 U.S.C. 102(b) as being anticipated by Wilton et al. (WO 2011/057350 A1, applicant’s citation).

Wilton et al. disclose an antisense oligonucleotide that induces exon 44 skipping and anneals to the target region +61+91 (thus necessarily encompassing +64+91, +62+89, and +62+85) in Table 33 as below:

H44A(+61+91)	GAG AAA CUG UUC AGC UUC UGU UAG CCA CUG A
--------------	---

The above antisense oligonucleotide comprises the base sequence of the entire SEQ ID NO:6 wherein T is replaced by U as claimed in the instant case.

Wilton et al. also disclose a 31-mer that comprises the base sequence of the entire SEQ ID NO:6, wherein T is replaced by U as below:

H44A(+59+89)	GAA ACU GUU CAG CUU CUG UUA GCC ACU GAU U
--------------	---

Wilton et al. teach that the antisense oligonucleotide comprises “phosphoromorpholidates, phosphoropiperazidates and phosphoramidates”, “N-2, N-6 and O-6 substituted purines”, and 5-methylcytosine substitutions and is chemically linked to “one or more moieties or conjugates that enhance the activity, cellular distribution or cellular uptake of the oligonucleotide.” See pages 24-25. They teach that the moieties comprise “a polyamine or a polyethylene glycol chain”. See page 25.

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Wilton et al. teach that the oligonucleotide is expressed from an expression vector. See page 29.

Wilton et al. teach that the antisense oligonucleotide is formulated as a pharmaceutical composition with a pharmaceutically acceptable carrier thus is useful for therapy and can be prepared as a kit. See pages 28-32.

Accordingly, all claim limitations are taught by Wilton et al.

Claims 1, 15-20, 32-37, and 41-59 are rejected under pre-AIA 35 U.S.C. 102(b) as being anticipated by Sazani et al. (WO 2010/048586 A1, applicant's citation).

Sazani et al. disclose a 25-mer PMO antisense oligonucleotide comprising SEQ ID NO:11 that induces human dystrophin exon 44 skipping, wherein the oligonucleotide comprises at least 17 consecutive nucleotides of SEQ ID NO:5 and SEQ ID NO:6 claimed in the instant case. See SEQ ID NO:11 as disclosed at page 79 as below:

Hu.DMD.Exon44.25.011 | AACTGTTTCAGCTTCTGTTAGCCAC | 11

Sazani et al. teach that the oligonucleotide comprises 5-methylcytidine or 2-methylthio-N6-isopentenyladenosine. See page 19.

Sazani et al. teach that "the T bases may be shown as U". See page 20.

Sazani et al. teach that the oligonucleotide is "conjugated to an arginine-rich polypeptide" or chemically linked to a polyethyleneglycol to promote uptake of the compound into cells. See pages 8-10.

Sazani et al. teach that the oligonucleotide is formulated as a pharmaceutical composition comprising one or more pharmaceutically acceptable carriers. See page 45.

Sazani et al. teach a kit comprising the oligonucleotide "packaged in a suitable container and instruction for its use." See page 12.

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Sazani et al. teach that the oligonucleotide can be delivered via an expression vector such as an adeno-associated viral vector or retroviral vector. See pages 30-31.

Accordingly, all claim limitations are taught by Sazani et al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit <http://www.uspto.gov/forms/>. The filing date of the application will determine what

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form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to <http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp>.

Claims 1, 18-19, 41, 45, 49, 54, and 57 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-32 of U.S. Patent No. 8,779,128 B2.

Although the claims at issue are not identical, they are not patentably distinct from each other because the instant claims are anticipated by the '128 patent claims. Note that the "oligomer" of the '128 patent claims necessarily encompasses SEQ ID NO:23 disclosed in the '128 specification, which defines that the oligomer is one of SEQ ID NOs:1-55 disclosed in Table 11, wherein SEQ ID NO:23 comprises at least 17 consecutive nucleotides of SEQ ID NO:6. Note that "those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent." See MPEP §804. See also *Pfizer Inc. v. Teva Pharmaceuticals USA Inc.*, 518 F.3d 1353, 86 USPQ2d 1001 (Fed. Cir. 2008), wherein the court expressed the following: "To the extent that Pfizer contends that we may not rely on the teachings of the specification or claims in the '165 patent to reject the claims of the '068 patent, we disagree. *See Geneva*, 349 F.3d at 1386. There is nothing that prevents us from looking to the specification to determine the proper scope of the claims."

Claims 1, 15-20, 32-37, and 41-59 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-32 of U.S. Patent No. 8,779,128 B2 in view of Sazani et al. (WO 2010/048586 A1, applicant's citation).

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Although the claims at issue are not identical, they are not patentably distinct from each other because the instant claims are an obvious variation of the '128 patent claims drawn to a morpholino-containing oligomer, which is defined to target “a splice site of a pre-mRNA” (see column 74, lines 55-63) such that the oligomer induces exon skipping of DMD pre-mRNA (see columns 83-84), wherein Sazani's SEQ ID NO:11 was known to induce human dystrophin exon 44 skipping. Hence, it would have been obvious to arrive at the instant claims over the '128 patent claims in view of Sazani et al.

Claims 1-2, 15, 17-20, 32, 34-35, and 41-59 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-32 of U.S. Patent No. 8,779,128 B2 in view of Wilton et al. (WO 2011/057350 A1, applicant's citation).

Although the claims at issue are not identical, they are not patentably distinct from each other because the instant claims are an obvious variation of the '128 patent claims drawn to a morpholino-containing oligomer, which is defined to target “a splice site of a pre-mRNA” (see column 74, lines 55-63) such that the oligomer induces exon skipping of DMD pre-mRNA (see columns 83-84), wherein Wilton's oligonucleotides comprising the base sequence of the claimed SEQ ID NO:6 were known to induce human dystrophin exon 44 skipping. Hence, it would have been obvious to arrive at the instant claims over the '128 patent claims in view of Wilton et al.

Claim Objections

Claim 3 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form. Note that the length range recited in the claim should be deleted as the range conflicts with the “consisting of” language.

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Conclusion

Claims 3 and 60-65 are free of the art of record and searched.

Claim 3 is objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANA SHIN whose telephone number is (571)272-8008. The examiner can normally be reached on Monday through Thursday, 7am-5:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin
Primary Examiner
Art Unit 1674

/DANA SHIN/
Primary Examiner, Art Unit 1674



UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/213,607	03/14/2014	Richard K. BESTWICK	AVN-013A	1039

959 7590 09/18/2014
NELSON MULLINS RILEY & SCARBOROUGH LLP
FLOOR 30, SUITE 3000
ONE POST OFFICE SQUARE
BOSTON, MA 02109

EXAMINER

SHIN, DANA H

ART UNIT	PAPER NUMBER
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1674

NOTIFICATION DATE	DELIVERY MODE
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09/18/2014

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipboston.docketing@nelsonmullins.com
chris.schlauch@nelsonmullins.com
ipqualityassuranceboston@nelsonmullins.com

Application No.
14/213,607
58134Applicant(s)
BESTWICK ET AL.**Office Action Summary**Examiner
DANA SHINArt Unit
1674AIA (First Inventor to File)
Status
No**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3-14-2014.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 1-42 is/are pending in the application.
 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☐ Claim(s) ____ is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☒ Claim(s) 1-42 are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
 Paper No(s)/Mail Date ____.
- 3) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. ____.
- 4) ☐ Other: ____.

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DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-38 and 41-42, drawn to an antisense oligonucleotide that induces human dystrophin exon 44 skipping, classified in CPC class C12N 15/113.
- II. Claim 39, drawn to a method of treating DMD, classified in A61K 38/00.
- III. Claim 40, drawn to use of an antisense molecule for manufacture of a medicament, classified in A61J 3/00.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and III are directed to related processes. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have different functions and effects. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions I and II-III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP

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§ 806.05(h). In the instant case the antisense oligonucleotide of group I can be used as a probe or primer.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and/or examination burden if restriction were not required because one or more of the following reasons apply:

1) the inventions have acquired a separate status in the art in view of the different classification;

2) the inventions require a different field of search (for example, searching different classes/subclasses or electronic sources, or employing different search queries);

3) the prior art applicable to one invention would not likely to be applicable to another invention;

4) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to

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petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 or pre-AIA 35 U.S.C. 103(a) of the other invention.

Election of Species

This application contains claims directed to the following patentably distinct species SEQ ID NOs:1-7. The species are independent or distinct because they are materially different. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, or a single grouping of patentably indistinct species, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 18 are generic.

There is a search and/or examination burden for the patentably distinct species as set forth above because at least the following reason(s) apply:

- 1) the species require a different field of search (for example, employing different search queries);
- 2) the prior art applicable to one species would not likely to be applicable to another species;
- 3) the species are likely to raise different non-prior art issues under 35 U.S.C. 112, first paragraph.

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Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species or grouping of patentably indistinct species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species or grouping of patentably indistinct species.

Should applicant traverse on the ground that the species, or groupings of patentably indistinct species from which election is required, are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing them to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 or pre-AIA 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be corrected in compliance with 37 CFR 1.48(a) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. A request to correct inventorship under 37 CFR 1.48(a) must be accompanied by an application data sheet in accordance with 37 CFR 1.76 that identifies each inventor by his or her legal name and by the processing fee required under 37 CFR 1.17(i).

Notice of Rejoinder

The examiner has required restriction between product or apparatus claims and process claims. Where applicant elects claims directed to the product/apparatus, and all product/apparatus claims are subsequently found allowable, withdrawn process claims that include all the limitations of the allowable product/apparatus claims should be considered for rejoinder. All claims directed to a nonelected process invention must include all the limitations of an allowable product/apparatus claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product/apparatus claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product/apparatus are found allowable, an otherwise proper restriction requirement between product/apparatus claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product/apparatus claim will not be rejoined. See MPEP § 821.04. Additionally, in order for rejoinder to occur, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product/apparatus claims. **Failure to do so**

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may result in no rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANA SHIN whose telephone number is (571)272-8008. The examiner can normally be reached on Monday through Thursday, 7am-5:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Babic can be reached on 571-272-8507. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin
Primary Examiner
Art Unit 1674

/DANA SHIN/
Primary Examiner, Art Unit 1674



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/213,629	03/14/2014	Edward M. KAYE	AVN-012ARCE	9624

123147 7590 05/23/2016
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

EXAMINER

POLIAKOVA-GEORGA, EKATERINA

ART UNIT	PAPER NUMBER
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1674

NOTIFICATION DATE	DELIVERY MODE
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05/23/2016

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipboston.docketing@nelsonmullins.com
chris.schlauch@nelsonmullins.com
ipqualityassuranceboston@nelsonmullins.com

Application No.
14/213,629
#: 58142Applicant(s)
KAYE, EDWARD M.**Office Action Summary**Examiner
KATE POLIAKOVAArt Unit
1674AIA (First Inventor to File)
Status
No**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02/25/2016 and 01/21/2016.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 1,27-29 and 33-54 is/are pending in the application.
 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1,27-29 and 33-54 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
 Paper No(s)/Mail Date 02/12/2016, 01/21/2016.
- 3) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. ____.
- 4) ☐ Other: ____.

Application/Control Number: 14/213,629
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Page 2

The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/21/2016 has been entered.

Status of Application, Amendments and/or Claims

Claims 1, 27-29, 33-54 are currently pending and are under examination.

Any rejection or objection not reiterated in this action is withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of pre-AIA 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 29, 35-38, 40, 46, 48 are rejected under pre-AIA 35 U.S.C. 102(a) as being anticipated by AVI BioPharma (Press Release, April 2012, pages 1-3, cited from IDS filed on 07/07/2015, item # 11).

The press release discloses treatment of Duchenne muscular dystrophy by once weekly infusion of eteplirsen at a dose of 30 mg/kg (see page 1).

Claims 1, 29, 35-38, 40, 46, 48, 52 are rejected under pre-AIA 35 U.S.C. 102(a) as being anticipated by Sarepta Therapeutics (Press Release, July 2012, pages 1-4, cited from IDS filed on 07/07/2015, item # 12).

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The press release discloses treatment of Duchenne muscular dystrophy by once weekly infusion of eteplirsen at a dose of 30 mg/kg, while disease progression was measured by 6 Minute Walk Test (see pages 1-3).

Claims 1, 29, 35-38, 40, 42, 46, 48, 52 are rejected under pre-AIA 35 U.S.C. 102(a) as being anticipated by Sarepta Therapeutics (Press Release, October 2012, pages 1-5, cited from IDS filed on 07/07/2015, item # 13).

The press release discloses treatment of Duchenne muscular dystrophy by once weekly infusion of eteplirsen at a dose of 30 mg/kg for 48 weeks, while disease progression was measured by 6 Minute Walk Test (see pages 1 and 3).

Claims 1, 29, 35-38, 40, 42, 43, 46, 48, 52 are rejected under pre-AIA 35 U.S.C. 102(a) as being anticipated by Sarepta Therapeutics (Press Release, December 2012, pages 1-4, cited from IDS filed on 07/07/2015, item # 14).

The press release discloses treatment of Duchenne muscular dystrophy by once weekly infusion of eteplirsen at a dose of 30 mg/kg, while disease progression was measured by 6 Minute Walk Test (see pages 1 and 2).

Claims 1, 29, 35-38, 40, 42, 46, 48 are rejected under pre-AIA 35 U.S.C. 102(a) as being anticipated by Sarepta Therapeutics (Drugs of the future, January 2013, vol.38, 1: 13-17, cited from IDS filed on 06/29/2015, item # 2).

The publication discloses treatment of Duchenne muscular dystrophy by once weekly infusion of eteplirsen at a dose of 30 mg/kg (see bridging paragraph between pages 15 and 16 and page 16).

Claims 1, 27-29, 33-38, 40, 45, 46, 48, 50 and 51 are rejected under pre-AIA 35 U.S.C. 102(b) as being anticipated by Clinical Trial NCT01396239 (ClinicalTrials.gov, published online on 07/15/2011, 4 pages, cited from IDS 10 pages long filed on 06/29/2015, item #23).

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Clinical Trial NCT01396239 discloses a method for treating Duchenne muscular dystrophy through induction of dystrophin expression by administration of eteplirsen in 50 mg/kg or 30 mg/kg dosing (see page 1) once weekly by single intravenous (i.v.) infusion to patients of 7 to 13 years old, having an out-of-frame deletion(s) that may be corrected by skipping exon 51 (see page 2), who receive treatment with oral corticosteroid for at least 24 weeks before eteplirsen treatment (see first paragraph on page 3).

Limitations of claims 36-38, 40 and claims 29 and 48 after “thereby” clause are expected to happen in the absence of evidence to the contrary.

Claims 1, 27-29, 33-43, 45-54 are rejected under pre-AIA 35 U.S.C. 102(b) as being anticipated by Clinical Trial NCT01540409 (ClinicalTrials.gov, published online on 02/23/2012, 4 pages, cited from IDS filed on 01/21/2016) as evidenced by Clinical Trial NCT01396239, above.

Clinical Trial NCT01540409 discloses a method for treating Duchenne muscular dystrophy through induction of dystrophin expression by administration of eteplirsen in 50 mg/kg or 30 mg/kg dosing (see page 2) once weekly by infusion to patients of 7 to 13 years old for 212 weeks (see page 1). The patient to administer treatment are the ones who finished previous Clinical Trial NCT01396239, referred to as Study 4658-US-201 (see page 1), who have an out-of-frame deletion(s) that may be corrected by skipping exon 51 (see page 2 of NCT01396239), who receive treatment with oral corticosteroid for at least 24 weeks before eteplirsen treatment (see first paragraph on page 3 of NCT01396239).

Clinical Trial NCT01540409 further discloses that ambulation is measured by North Star Ambulatory Assessment (see page 2), disease progression is measured by 6 Minute Walk Test and 9-Hole Peg Test (see page 2), pulmonary function is measured by pulmonary function test (see page 2) and level of dystrophin protein is measured by Western Blot analysis (see page 2).

Limitations of claims 36-38, 40 and claims 29 and 48 after “thereby” clause are expected to happen in the absence of evidence to the contrary.

Claim Rejections - 35 USC § 103

Application/Control Number: 14/213,629

Page 5

Art Unit: 1674

The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 44 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Clinical Trial NCT01396239, above, and in further view of Manzur et al (Cochrane Database Syst Rev, 2004, 2: 1-71, cited from IDS filed on 07/21/2015).

Teachings from Clinical Trial are discussed above.

Manzur et al teach that treatment of Duchenne muscular dystrophy with prednisolone or prednisone provides benefit to a patient (see Abstract and second column on page 4).

It would have been obvious to one with ordinary skill in the art at the time of the invention to use both treatments for Duchenne muscular dystrophy as described by Clinical Trial and Manzur et al. One of the ordinary skill in the art would be motivated to do so because the treatments are provided for the same disease. It is obvious to combine things known separately to have same effect (see *In re Kerkhoven*, MPEP 2144.06).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645

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(Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP §§ 706.02(l)(1) - 706.02(l)(3) for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/forms/. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to <http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp>.

Claims 1, 27-29, 33-54 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1, 5-7, 12, 13, 15, 19, 20, 27-34, 40-48 of copending Application No. 14/214,567 (reference application). Although the claims at issue are not identical, they are not patentably distinct from each other because claims cover overlapping subject matter: treatment of Duchenne muscular dystrophy by administering eteplirsen intravenously as a single dose in combination with oral corticosteroid (claims from '567).

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed 01/21/2016 have been fully considered but they are not persuasive.

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Concerning 102(a) rejection Applicant argues that the publications are not available as prior art because inventor assigned rights to Sarepta Therapeutics, a publisher of the publications. In reply Applicant is required to provide declaration or affidavit under 37 CFR 1.132 showing that the reference invention is not by "another." (see MPEP 706.02(b)). Until such affidavit or declaration is submitted, the rejection is maintained.

Concerning 102(b) rejection Applicant argues that the reference does not teach a variety of specific outcomes of methods claimed, such outcomes are included in the claims. In reply the prior art publication teaches the active step of the methods claimed, administering eteplirsen in required dosage to defined group of patients, therefore outcomes of such administration are expected to happen in the absence of evidence to the contrary. The argument that such outcomes are probable and not inevitable is not persuasive, because there is no evidence that the required outcomes are not going to occur. Rejection is maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATE POLIAKOVA whose telephone number is (571)270-5257. The examiner can normally be reached on Monday-Friday 8.30-5.00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia (Anna) Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 14/213,629

Page 8

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KATE POLIAKOVA
Examiner
Art Unit 1674

/KATE POLIAKOVA/
Examiner, Art Unit 1674



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/213,629	03/14/2014	Edward M. KAYE	AVN-012A	9624

123147 7590 08/21/2015
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

EXAMINER
POLIAKOVA-GEORGAN, EKATERINA

ART UNIT	PAPER NUMBER
1674	

NOTIFICATION DATE	DELIVERY MODE
08/21/2015	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipboston.docketing@nelsonmullins.com
chris.schlauch@nelsonmullins.com
ipqualityassuranceboston@nelsonmullins.com

Application No.
14/213,629
#: 58151Applicant(s)
KAYE, EDWARD M.**Office Action Summary**Examiner
KATE POLIAKOVAArt Unit
1674AIA (First Inventor to File)
Status
No**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06/29/2015.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 1 and 24-34 is/are pending in the application.
 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1 and 24-34 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
 Paper No(s)/Mail Date 06/29/2015, 07/07/2015, 07/21/2015.
- 3) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. ____.
- 4) ☐ Other: ____.

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The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

Status of Application, Amendments and/or Claims

Claims 1, 24-34 are currently pending and are under examination, claims 2-23 are cancelled.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of pre-AIA 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 24-26, 29-32 are rejected under pre-AIA 35 U.S.C. 102(a) as being anticipated by AVI BioPharma (Press Release, April 2012, pages 1-3, cited from IDS filed on 07/07/2015, item # 11).

The press release discloses treatment of Duchenne muscular dystrophy by once weekly infusion of eteplirsen (see page 1).

Claims 1, 24-26, 29-32 are rejected under pre-AIA 35 U.S.C. 102(a) as being anticipated by Sarepta Therapeutics (Press Release, July 2012, pages 1-4, cited from IDS filed on 07/07/2015, item # 12).

The press release discloses treatment of Duchenne muscular dystrophy by once weekly infusion of eteplirsen (see pages 1 and 2).

Claims 1, 24-26, 29-32 are rejected under pre-AIA 35 U.S.C. 102(a) as being anticipated by Sarepta Therapeutics (Press Release, October 2012, pages 1-5, cited from IDS filed on 07/07/2015, item # 13).

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The press release discloses treatment of Duchenne muscular dystrophy by once weekly infusion of eteplirsen (see pages 1 and 3).

Claims 1, 24-26, 29-32 are rejected under pre-AIA 35 U.S.C. 102(a) as being anticipated by Sarepta Therapeutics (Press Release, December 2012, pages 1-4, cited from IDS filed on 07/07/2015, item # 14).

The press release discloses treatment of Duchenne muscular dystrophy by once weekly infusion of eteplirsen (see pages 1 and 2).

Claims 1, 24-26, 29-32 are rejected under pre-AIA 35 U.S.C. 102(a) as being anticipated by Sarepta Therapeutics (Drugs of the future, January 2013, vol.38, 1: 13-17, cited from IDS filed on 06/29/2015, item # 2).

The publication discloses treatment of Duchenne muscular dystrophy by once weekly infusion of eteplirsen (see bridging paragraph between pages 15 and 16 and page 16).

Claims 1, 24-34 are rejected under pre-AIA 35 U.S.C. 102(b) as being anticipated by Clinical Trial NCT01396239 (ClinicalTrials.gov, published online on 07/15/2011, 4 pages, cited from IDS 10 pages long filed on 06/29/2015, item #23).

Clinical Trial NCT01396239 discloses a method for treating Duchenne muscular dystrophy through induction of dystrophin expression by administration of eteplirsen in 50 mg/kg or 30 mg/kg dosing (see page 1) once weekly by single intravenous (i.v.) infusion to patients of 7 to 13 years old, having an out-of-frame deletion(s) that may be corrected by skipping exon 51 (see page 2), who receive treatment with oral corticosteroid for at least 24 weeks before eteplirsen treatment (see first paragraph on page 3).

Double Patenting

A rejection based on double patenting of the “same invention” type finds its support in the language of 35 U.S.C. 101 which states that “whoever invents or discovers any new and useful process...

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may obtain a patent therefor..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the claims that are directed to the same invention so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1, 24, 25, 28-31, 34 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-4, 6, 15-18, 20 of copending Application No. 14/214,567. This is a provisional statutory double patenting rejection since the claims directed to the same invention have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims

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an invention made as a result of activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit <http://www.uspto.gov/forms/>. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to <http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-l.jsp>.

Claims 26, 27, 32, 33 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 2, 3, 6, 22, 23 and 26 of copending Application No. 14/214,567. Although the claims at issue are not identical, they are not patentably distinct from each other because claims cover overlapping subject matter: treatment of Duchenne muscular dystrophy by administering eteplirsen intravenously as a single dose in combination with oral corticosteroid (claims from '567). This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed 06/29/2015 have been fully considered but they are not persuasive.

Previous 112 and 103 rejections are withdrawn because of new amendments, therefore arguments are moot.

Double patenting rejection is maintained.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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Art Unit: 1674

Page 6

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATE POLIAKOVA whose telephone number is (571)270-5257. The examiner can normally be reached on Monday-Friday 8.30-5.00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KATE POLIAKOVA
Examiner
Art Unit 1674

/KATE POLIAKOVA/
Examiner, Art Unit 1674

/Tracy Vivlemore/
Primary Examiner, Art Unit 1674



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/213,629	03/14/2014	Edward M. KAYE	AVN-012A	9624

123147 7590 12/29/2014
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

EXAMINER
POLIAKOVA-GEORGAN, EKATERINA

ART UNIT	PAPER NUMBER
1674	

NOTIFICATION DATE	DELIVERY MODE
12/29/2014	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipboston.docketing@nelsonmullins.com
chris.schlauch@nelsonmullins.com
ipqualityassuranceboston@nelsonmullins.com

Application No.
14/213,629
#: 88138Applicant(s)
KAYE, EDWARD M.**Office Action Summary**Examiner
KATE POLIAKOVAArt Unit
1674AIA (First Inventor to File)
Status
No**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07/24/2014.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 1-23 is/are pending in the application.
 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-23 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
 Paper No(s)/Mail Date ____.
- 3) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. ____.
- 4) ☐ Other: ____.

Application/Control Number: 14/213,629
Art Unit: 1674

Page 2

The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

Status of Application, Amendments and/or Claims

Claims 1-23 are currently pending and are under examination.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) is acknowledged.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of 35 U.S.C. 112(b):

(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-4 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

Claims 2-4 recite the limitation "the number of dystrophin-positive fibers" in the first line of each claim. There is insufficient antecedent basis for this limitation in the claim.

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Art Unit: 1674

Page 3

Claim Rejections - 35 USC § 103

The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-23 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Sazani et al (US 2010/0130591, May 2010) and in further view of de Kimpe et al (US 2011/0294753, December 2011).

Regarding claims 1-7, 14 and 15 Sazani et al teach a method of treatment of Duchenne muscular dystrophy by administering antisense oligonucleotide, 20-35 bases long, (see paragraphs [0049-0050]), comprising at least 12 consecutive bases complementary to a target region in an exon of dystrophin gene (see paragraph [0018]), which can be administered to the patient in the range of 0.0001 to 100 mg/kg (see paragraph [0229]). Sazani et al disclose that dystrophin expression by administering antisense oligonucleotide can be increased from 1 to 100% (see paragraph [0112]). Sazani et al is silent concerning improvement of stable walking distance in a 6 min walk test, but such improvement is expected based on increase of dystrophin expression and in the absence of evidence to the contrary.

Regarding claim 8 Sazani et al teach that antisense oligonucleotide can be substantially uncharged (see paragraph [0050]).

Regarding claims 9-11 Sazani et al teach that antisense oligonucleotide can comprise morpholino subunits and phosphorus-containing intersubunit linkages joining a morpholino nitrogen of one subunit to a 5' exocyclic carbon of an adjacent subunit (see paragraph [0018]), such linkages can be substantially uncharged (see paragraph [0024]) and can be phosphorodiamidate (see paragraph [0059] and Figure 1A).

Regarding claims 12 and 13 Sazani et al teach that antisense oligonucleotide can be conjugated to an arginine-rich peptide (see paragraph [0040]).

Application/Control Number: 14/213,629

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Regarding claim 16 Sazani et al teach that antisense oligonucleotide can target exons 44, 45, 46, 50, 51, 52, 53 and 55 of human dystrophin gene (see paragraphs [0027-0029, 0033-0036, 0038]).

Regarding claims 17-19 Sazani et al teach that antisense oligonucleotide can be of SEQ ID NO: 588 (see paragraph [0064] and sequence listing), which is fully identical to instant SEQ ID NO: 1.

Regarding claim 20 Sazani et al teach that the composition comprising antisense oligonucleotide can further comprise isotonic saline (see paragraph [0196]), which is known in the art to be a different name for phosphate buffered saline.

Regarding claims 21 and 22 Sazani et al teach systemic administration of oligonucleotide (see paragraph [0193]) and once a week administration (see paragraph [0230]) by infusion (see paragraph [0224]).

Sazani et al teach a wide range of possible administration dosage (0.0001 to 100 mg/kg) and do not specifically point out the dosage of 30 mg/kg or 50 mg/kg. Sazani et al do not teach additional administration of steroid to human subject.

De Kimpe et al teach that antisense oligonucleotides for treatment of Duchenne muscular dystrophy can be administered together with steroid, such administration enhancing skipping frequency of oligonucleotide (see paragraph [0040]).

It would have been obvious to one with ordinary skill in the art at the time of the invention to use specific dosages of 30 mg/kg or 50 mg/kg of antisense oligonucleotides described by Sazani et al, because those dosages lie inside the range of dosages suitable for administration as taught by Sazani et al. One of the art would be motivated to use those dosages because Sazani et al teach the specific range of dosages, effective for treatment, therefore any dosage falling in the range is expected to be efficient for disease treatment.

It would have been obvious to one with ordinary skill in the art at the time of the invention to add steroid to antisense oligonucleotides taught by Sazani et al for treatment of Duchenne muscular dystrophy as taught by de Kimpe et al. One of the art would be motivated to do so, because de Kimpe et al teach that addition of steroid increases effectiveness of antisense oligonucleotide in the disease treatment.

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit <http://www.uspto.gov/forms/>. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to <http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp>.

Claims 1, 5, 6, 17-19 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-4, 7, 8-11, 14-18 and 21-24 of copending Application No. 14/214,567. Although the claims at issue are not identical, they are not patentably distinct from each other because claims cover overlapping subject matter: treatment of Duchenne muscular dystrophy by administering eteplirsen (claims from '567), which is the same as SEQ ID NO: 1 from instant claim 18. Instant

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specification also teach administration of eteplirsen intravenously and once a week (see paragraph [0221]). Further claims from '567 anticipate instant claims 1, 5, 6, 17 and 19, because claims from '567 use a species, eteplirsen, of a wide genus of instant claims 1, 5, 6, 17 and 19, in a method of treatment of the disease.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATE POLIAKOVA whose telephone number is (571)270-5257. The examiner can normally be reached on Monday-Friday 8.30-5.00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KATE POLIAKOVA/
Examiner, Art Unit 1674

/Mark Shibuya/
Supervisory Patent Examiner, Art Unit 1678



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/213,641	03/14/2014	Richard K. BESTWICK	AVN-017	7957

123147 7590 08/01/2016
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

EXAMINER

SHIN, DANA H

ART UNIT	PAPER NUMBER
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1674

NOTIFICATION DATE	DELIVERY MODE
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08/01/2016

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipboston.docketing@nelsonmullins.com
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ipqualityassuranceboston@nelsonmullins.com

Application No.
14/213,641
58165Applicant(s)
BESTWICK ET AL.**Office Action Summary**Examiner
DANA SHINArt Unit
1674AIA (First Inventor to File)
Status
No**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3-16-2016.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 1,16-19,33-35,44,45,47-53 and 60-64 is/are pending in the application.
 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1,16-19,33-35,44,45,47-53 and 60-64 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
 Paper No(s)/Mail Date ____.
- 3) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date ____.
- 4) ☐ Other: ____.

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DETAILED ACTION

The present application is being examined under the pre-AIA first to invent provisions.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 16, 2016 has been entered.

Status of Claims

Claims 1, 16-19, 33-35, 44-45, 47-53, and 60-64 are currently pending and under examination on the merits in the instant case.

Claim Objections

Claims 19, 33-35, 47, and 62 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 1, 16-18, 44, and 61. Note that the antisense oligonucleotide sequences/structures of (i), (ii), and (iii) of the substantially identical claims are the same, despite the difference in the claim language.

Claims 51-53 and 64 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 48-50 and 63. Note that the antisense oligonucleotide sequences/structures of (i), (ii), and (iii) of the substantially identical claims are the same, despite the difference in the claim language.

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When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112(a):

(a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of the first paragraph of pre-AIA 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 61-64 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or for pre-AIA the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claims require that the antisense oligonucleotide is conjugated to a triethyleneglycol moiety via a piperazinyl moiety.

Applicant pointed out paragraphs 0029, 0103, 0095, and 0149 of the published application and Figures 1B-1C for support. Contrary to applicant's argument, none of the

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paragraphs and Figures support the claimed structure. In fact, the application as originally filed does not describe a “**tri**ethyleneglycol” moiety. The application at best discloses the genus “**poly**ethylene glycol”. See paragraph 0029. Further, the application does not describe that the specific “triethyleneglycol” is conjugated to the oligonucleotide via the specific “piperazinyl” moiety. The application at best discloses that PEG (polyethylene glycol) is “chemically linked” to the oligonucleotide. See original claim 18.

Accordingly, claims 61-64 introduce new matter which is not adequately described in the application as originally filed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of pre-AIA 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 16-19, 33-35, 44-45, 47-53, and 60 are rejected under pre-AIA 35 U.S.C. 102(a) and 102(e) as being anticipated by Popplewell et al. (US 2012/0065244 A1, of record).

Popplewell discloses PMO antisense oligonucleotides that cause exon 53 skipping of human dystrophin, wherein the oligonucleotides comprise at least 25 consecutive nucleotides of SEQ ID NO:12, wherein X is T or U as shown below:

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(SEQ ID NO: 12)
XXG CCX CCG GXX CXG AAG GXG XXC XKG XAC,

As such, Popplewell inherently discloses a 28-mer that is identical to SEQ ID NO:15 claimed in the instant case; a 27-mer that is identical to SEQ ID NO:16 claimed in the instant case; a 26-mer that is identical to SEQ ID NO:17 claimed in the instant case; and a 25-mer that is identical to SEQ ID NO:18 claimed in the instant case.

Popplewell teaches that the oligonucleotide is formulated as a pharmaceutical composition comprising pharmaceutically acceptable carrier or polyethylene glycol or “an arginine-rich cell penetrating peptide (CPP)”. See paragraphs 0032, 0034-0035.

Accordingly, all claim limitations are taught by Popplewell et al.

Response to Arguments

Applicant's arguments filed on March 16, 2016 have been fully considered but they are not persuasive. Applicant argues that the claims are not anticipated by Popplewell because Popplewell's SEQ ID NO:12 is not identical to any one of SEQ ID NOs:15-17 claimed in the instant case and because Popplewell does not disclose any oligonucleotides of 26, 27, or 28 bases in length. Contrary to applicant's argument, the mere fact that Popplewell's reference does not expressly spell out the nucleotide sequences of 26, 27, and 28 nucleotides in length is not sufficient to render the claims novel. As explained in the rejection above, Popplewell expressly taught making PMO antisense oligonucleotides comprising at least 25 consecutive nucleotides of SEQ ID NO:12, wherein X is T or U. As such, Popplewell inherently discloses the following PMO-modified DNA oligonucleotides of 25-29 nucleotides in length comprising at least 25-mer of SEQ ID NO:12.

TTGCCTCCGGTTCTGAAGGTGTTCTTGTA

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TTGCCTCCGGTTCTGAAGGTGTTCTTGT
TTGCCTCCGGTTCTGAAGGTGTTCTTG
TTGCCTCCGGTTCTGAAGGTGTTCTT
TTGCCTCCGGTTCTGAAGGTGTTCT
TGCCTCCGGTTCTGAAGGTGTTCTTGAC
TGCCTCCGGTTCTGAAGGTGTTCTTGTA
TGCCTCCGGTTCTGAAGGTGTTCTTGT
TGCCTCCGGTTCTGAAGGTGTTCTTG
TGCCTCCGGTTCTGAAGGTGTTCTT
GCCTCCGGTTCTGAAGGTGTTCTTGAC (identical to SEQ ID NO:15 claimed)
GCCTCCGGTTCTGAAGGTGTTCTTGTA
GCCTCCGGTTCTGAAGGTGTTCTTGT
GCCTCCGGTTCTGAAGGTGTTCTTG
CCTCCGGTTCTGAAGGTGTTCTTGAC (identical to SEQ ID NO:16 claimed)
CCTCCGGTTCTGAAGGTGTTCTTGTA
CCTCCGGTTCTGAAGGTGTTCTTGT
CTCCGGTTCTGAAGGTGTTCTTGAC (identical to SEQ ID NO:17 claimed)
CTCCGGTTCTGAAGGTGTTCTTGTA
TCCGGTTCTGAAGGTGTTCTTGAC

In addition, Popplewell inherently discloses PMO-modified oligonucleotides identical to SEQ ID NOs:15-17, wherein thymines are uracils in view of the explicit teaching that X is either T or U. Hence, claims 45 and 60 are also inherently anticipated.

“If one of ordinary skill in the art is able to “at once envisage” the specific compound within the generic chemical formula, **the compound is anticipated**. One of ordinary skill in the

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art must be able to draw the structural formula or write the name of each of the compounds included in the generic formula before any of the compounds can be “at once envisaged.”” (emphasis added). See MPEP §2131.02.

In the instant case, one of ordinary skill in the art is able to “at once envisage” or “write” the nucleotide sequences of all PMO modified DNA oligonucleotides comprising at least 25-mer of Popplewell’s SEQ ID NO:12. Hence, the instantly claimed compound is anticipated.

See *In re Petering*, 301 F.2d 676, 133 USPQ 275 (CCPA 1962), wherein the court stated the following: “We think the Karrer patent, as a printed publication, *describes* to one skilled in this art not only the broad class but also this much more limited class within that broad class, and we think it is immaterial that Karrer did not expressly spell out the limited class as we have done here. It is our opinion that one skilled in this art would, on reading the Karrer patent, at once envisage *each member* of this limited class, even though this skilled person might not at once define in his mind the formal boundaries of the class as we have done here.” (original emphasis).

Analogous to the Karrer patent at issue in the *Petering* case, the Popplewell publication “describes” to one of ordinary skill in the art “each member” of PMO modified DNA oligonucleotides comprising at least 25-mer of Popplewell’s SEQ ID NO:12, although Popplewell did not expressly spell out the oligonucleotide sequence species.

As such, it is clear that the instantly claimed nucleotide sequences are inherently taught by Popplewell. Accordingly, this rejection is hereby reiterated.

Claim Rejections - 35 USC § 103

The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under pre-AIA 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of pre-AIA 35 U.S.C. 103(c) and potential pre-AIA 35 U.S.C. 102(e), (f) or (g) prior art under pre-AIA 35 U.S.C. 103(a).

Claims 1, 16-19, 33-35, 44-45, 47-53, and 60-64 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Popplewell et al. (US 2012/0065244 A1, of record) in view of Iversen et al. (US 2007/0265215 A1, of record).

Popplewell inherently discloses PMO oligonucleotides of SEQ ID NOs:15, 16, and 17 as explained in the 102 rejections, which are fully incorporated by reference herein thus will not be repeated. As such, instantly claimed SEQ ID NOs:15-17 are neither novel nor nonobvious over the prior art.

Popplewell does not teach conjugating a triethyleneglycol moiety to the PMO oligonucleotide via a piperazine moiety.

It was routine in the art at the time of the invention to attach a triethyleneglycol moiety to a PMO antisense oligonucleotide via a piperazine linking group so as to enhance the solubility of the PMO antisense oligonucleotide as taught by Iversen et al. See paragraphs 0093, 0126; claims 17, 20-21.

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Taken together, one of ordinary skill in the art would have been motivated at the time the invention was made to utilize Iversen's teaching when making Popplewell's human dystrophin exon 53 skipping PMO oligonucleotides comprising at least 25-mer of SEQ ID NO:12, with a reasonable expectation of success, so as to enhance the solubility of the PMO antisense oligonucleotide.

Accordingly, claims 1, 16-19, 33-35, 44-45, 47-53, and 60-64 taken as a whole would have been *prima facie* obvious at the time of the invention.

Response to Arguments

Applicant's arguments filed on March 16, 2016 have been fully considered but they are not persuasive. Applicant argues that the claims are not obvious because the claimed sequences are not taught by the cited references. Contrary to applicant's argument, instantly claimed SEQ ID NOs:15-17 are neither novel nor nonobvious because the nucleotide sequences are inherently disclosed by Popplewell as explained hereinabove, which is fully incorporated by reference thus will not be repeated.

Applicant merely asserts that the examiner failed to provide a motivation why one of ordinary skill in the art would have modified the cited references to arrive at the claimed invention. Contrary to applicant's assertion, the examiner has clearly set forth the motivation to combine the cited references to arrive at the claimed invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible

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harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP §§ 706.02(l)(1) - 706.02(l)(3) for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

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Claims 1, 16-19, 33-35, 44-45, 47-53, and 60-64 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-32 of U.S. Patent No. 8,779,128 B2 in view of Popplewell et al. (US 2012/0065244 A1, of record) and Iversen et al. (US 2007/0265215 A1, of record).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are encompassed by and obvious over the '128 patent claims, because making a PMO oligonucleotide of SEQ ID NOs:15-17 was known in the art as taught by Popplewell and because attaching a triethyleneglycol moiety to a PMO antisense oligonucleotide via a piperazine linking group was known to be useful when making a PMO antisense oligonucleotide as taught by Iversen.

Claims 1, 16-19, 33-35, 44-45, 47-53, and 60-64 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-17 of copending U.S. Application No. 14/776,533.

The instant claims are anticipated by the '533 claims. Note that SEQ ID NOs:2-4 claimed in the '533 claims are 100% identical to SEQ ID NOs:15-17 claimed in the instant claims, respectively. In addition, note that the structures claimed in claim 16 of the '533 application has a triethyleneglycol moiety conjugated via a piperazine moiety. Accordingly, the instant claims are anticipated by the '533 claims.

Conclusion

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANA SHIN whose telephone number is (571)272-8008. The examiner can normally be reached on Monday through Thursday, 7am-5:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin
Primary Examiner
Art Unit 1674

/DANA SHIN/
Primary Examiner, Art Unit 1674



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/213,641	03/14/2014	Richard K. BESTWICK	AVN-017	7957

123147 7590 10/16/2015
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

EXAMINER

SHIN, DANA H

ART UNIT	PAPER NUMBER
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1674

NOTIFICATION DATE	DELIVERY MODE
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10/16/2015

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipboston.docketing@nelsonmullins.com
chris.schlauch@nelsonmullins.com
ipqualityassuranceboston@nelsonmullins.com

Application No.
14/213,641
38178Applicant(s)
BESTWICK ET AL.**Office Action Summary**Examiner
DANA SHINArt Unit
1674AIA (First Inventor to File)
Status
No**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9-29-2015.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 1,16-19,33-35,44,45,47-53 and 60-64 is/are pending in the application.
 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1,16-19,33-35,44,45,47-53 and 60-64 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
 Paper No(s)/Mail Date ____.
- 3) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date ____.
- 4) ☐ Other: ____.

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DETAILED ACTION

The present application is being examined under the pre-AIA first to invent provisions.

Status of Application/Amendment/Claims

This Office action is in response to the communications filed on September 29, 2015.

Currently, claims 1, 16-19, 33-35, 44-45, 47-53, and 60-64 are pending and under examination on the merits in the instant application.

The following rejections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

Response to Arguments and Amendments

Withdrawn Rejections

Any rejections not repeated in this Office action are hereby withdrawn.

New Rejections Necessitated by Amendments

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112(a):

(a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of the first paragraph of pre-AIA 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

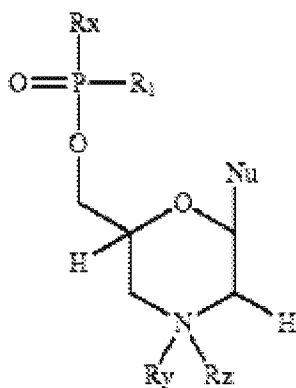
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Claims 61-64 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or for pre-AIA the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant pointed out paragraphs 0120 and 0129 of the published application for support, which are copied below:

[0120] In preferred embodiments, the invention provides an oligonucleotide having a sequence of nucleotides having a formula:



[0129] Rx is selected from the group consisting of sarcosinamide, hydroxyl, a nucleotide, a cell penetrating peptide moiety, and piperazinyl;

The two paragraphs at best describe a formula wherein Rx is sarcosinamide, hydroxyl, a nucleotide, a cell penetrating peptide moiety, or piperazinyl.

The paragraphs do not describe that a triethyleneglycol moiety is conjugated to an oligonucleotide via a piperazinyl moiety as now claimed.

Accordingly, claims 61-64 introduce new matter which was not adequately described in the specification as originally filed.

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Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 16-19, 33-35, 44-45, 47-53, and 60 are rejected under pre-AIA 35 U.S.C. 102(b) as being anticipated by Watanabe et al. (WO 2012/029986 A1; English translation attached).

Watanabe et al. disclose a dystrophin exon 53 skipping PMO antisense oligonucleotide SEQ ID NO:18, which is identical to SEQ ID NO:18. See page 11 disclosing the following:

5'-GCCTCCGGTTCTGAAGGTGTTCTTG-3' | SEQ ID NO: 18

Watanabe et al. teach that the PMO oligonucleotide is linked to a carrier moiety or a pharmaceutically acceptable carrier such as PEG, arginines, and PEI. See pages 19-20, 31-32; claims 1, 6-7, 10, 12-13 at pages 64-65.

Watanabe et al. teach that the oligonucleotide can comprise uracil. See page 14.

Accordingly, all claim limitations are taught by Watanabe et al.

Claims 1, 16-19, 33-35, 44-45, 47-53, and 60 are rejected under pre-AIA 35 U.S.C. 102(a) and 102(e) as being anticipated by Popplewell et al. (US 2012/0065244 A1, of record).

Popplewell et al. disclose PMO antisense oligonucleotides that cause exon 53 skipping of human dystrophin, wherein the oligonucleotides comprise at least 25 consecutive nucleotides of SEQ ID NO:12, wherein X is T or U as shown below:

{SEQ ID NO: 12}
XXG CXX CCG GXX CXG AAG GXG XXC XXG XAC,

As such, Popplewell et al. disclose a 28-mer that is identical to SEQ ID NO:15 claimed in the instant case; a 27-mer that is identical to SEQ ID NO:16 claimed in the instant case; a 26-mer

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that is identical to SEQ ID NO:17 claimed in the instant case; and a 25-mer that is identical to SEQ ID NO:18 claimed in the instant case.

Popplewell et al. teach that the oligonucleotide is formulated as a pharmaceutical composition comprising pharmaceutically acceptable carrier or polyethylene glycol or “an arginine-rich cell penetrating peptide (CPP)”. See paragraphs 0032, 0034-0035.

Accordingly, all claim limitations are taught by Popplewell et al.

Claim Rejections - 35 USC § 103

The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under pre-AIA 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of pre-AIA 35 U.S.C. 103(c) and potential pre-AIA 35 U.S.C. 102(e), (f) or (g) prior art under pre-AIA 35 U.S.C. 103(a).

Claims 61-64 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Watanabe et al. (WO 2012/029986 A1; English translation attached) and Popplewell et al. (US 2012/0065244 A1, of record) in view of Iversen et al. (US 2007/0265215 A1).

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Watanabe et al. and Popplewell et al. disclose the claimed invention of claims 18, 35, 50, and 53 as explained in the 102 rejections, which are fully incorporated by reference herein thus will not be repeated.

It was routine in the art at the time of the invention to attach a triethyleneglycol moiety to a PMO antisense oligonucleotide via a piperazine linking group so as to enhance the solubility of the PMO antisense oligonucleotide as taught by Iversen et al. See paragraphs 0093, 0126; claims 17, 20-21.

Taken together, one of ordinary skill in the art would have been motivated to utilize Iversen's teaching when making Watanabe's PMO oligonucleotide or Popplewell's PMO oligonucleotide, with a reasonable expectation of success, so as to enhance the solubility of the PMO antisense oligonucleotide.

Accordingly, claims 61-64 taken as a whole would have been *prima facie* obvious at the time of the invention.

Double Patenting

The text of the judicially created doctrine not included in this action can be found in a prior Office action.

Claims 1, 16-19, 33-35, 44-45, 47-53, and 60-64 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-32 of U.S. Patent No. 8,779,128 B2 in view of Watanabe et al. (WO 2012/029986 A1; English translation attached), Popplewell et al. (US 2012/0065244 A1, of record), and Iversen et al. (US 2007/0265215 A1).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are encompassed by and obvious over the '128 patent claims, because making a PMO oligonucleotide of SEQ ID NOs:15-18 was known in the art as

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taught by Watanabe et al. and Popplewell et al., and because attaching a triethyleneglycol moiety to a PMO antisense oligonucleotide via a piperazine linking group was known to be useful when making a PMO antisense oligonucleotide as taught by Iversen et al.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANA SHIN whose telephone number is (571)272-8008. The examiner can normally be reached on Monday through Thursday, 7am-5:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin
Primary Examiner
Art Unit 1674

/DANA SHIN/
Primary Examiner, Art Unit 1674

Notice of References Cited	Application/Control No. 14/213,641	Applicant(s)/Patent Under Reexamination BESTWICK ET AL.	
	Examiner DANA SHIN	Art Unit 1674	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-2007/0265215 A1	11-2007	Iversen; Patrick L.	C12N15/111	514/44A
	B	US-				
	C	US-				
	D	US-				
	E	US-				
	F	US-				
	G	US-				
	H	US-				
	I	US-				
	J	US-				
	K	US-				
	L	US-				
	M	US-				

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N	WO 2012029986 A1	03-2012	JP	WATANABE et al.	C12N15/111
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Filed

36187

PTO/SB/08a (03-15)

Approved for use through 07/31/2016. OMB 0651-0031

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		14213641	
	Filing Date		2014-03-14	
	First Named Inventor	Richard K. BESTWICK		
	Art Unit	1674		
	Examiner Name	D. H. Shin		
	Attorney Docket Number	AVN-017		

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Art Unit	1674
Examiner Name	D. H. Shin
Attorney Docket Number	AVN-017

1	Confirmation of Dystrophin Exon 52 Deletion in Cell Line R1809 Laboratory; Notebook Entry, Pages 3, Exhibit Number 1168 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
2	Confirmatory Study of Eteplirsén in DMD Patients, An Open-Label, Multi-Center, 48-Week Study With a Concurrent Untreated Control Arm to Evaluate the Efficacy and Safety of Eteplirsén in Duchenne Muscular Dystrophy ,Clinical Trials.gov, Clinical Trial Identifier NCT02255552, October 1, 2014, 3 pages	<input type="checkbox"/>
3	Confirmatory Study of Eteplirsén in DMD Patients, An Open-Label, Multi-Center, 48-Week Study With a Concurrent Untreated Control Arm to Evaluate the Efficacy and Safety of Eteplirsén in Duchenne Muscular Dystrophy, Clinical Trials.gov, Clinical Trial Identifier NCT02255552, May 26, 2015, 3 pages.	<input type="checkbox"/>
4	Coolidge v. Efendic, 2008 WL 2080735, Int. No. 105,457 (BPAI May 16, 2008), 42 pages, (Academisch Ziekenhuis Leiden Exhibit 1235, filed May 5, 2015 in Interference 106007 and 106008).	<input type="checkbox"/>
5	COREY, David R. et al., "Morpholino antisense oligonucleotides: tools for investigating vertebrate development," Genome Biology, Vol. 2(5):1015.1 - 1015.3 (2001) (Exhibit Number 1026 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
6	Corrected Priority Statement filed by UWA in Int. No. 106,008 (as PN 219),Pages 5, Exhibit Number 1002 filed in Interference 106,013 on February 17, 2015.	<input type="checkbox"/>
7	Cortes, Jesus J., et al., "Mutations in the conserved loop of human U5 snRNA generate use of novel cryptic 5' splice sites in vivo," EMBO J., Vol. 12, No. 13, pp. 5181-5189 (1993), Exhibit Number 1187 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
8	CROOKE, Stanley T., Antisense Drug Technology, Principles, Strategies, and Applications, Marcel Dekker, Inc., New York, Chapters 15 and 16, pages 375-389, 391-469 (2001) (Exhibit Number 2075 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
9	Curriculum Vitae of Judith van Deutekom, Pages 6, Exhibit Number 1126 filed in interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
10	Curriculum Vitae, Erik Joseph Sontheimer, 18 pages, dated September 29, 2014 (Exhibit Number 1013 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
11	CV, Professor Matthew J.A. Wood, 3 pages (Exhibit Number 2003 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>

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12	DAVIS, Richard J. et al., "Fusion of PAX7 to FKHR by the Variant t(1;13)(p36;q14) Translocation in Alveolar Rhabdomyosarcoma," Cancer Research, Vol. 54:2869-2872 (1994) (Exhibit Number 1027 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
13	DE ANGELIS, Fernanda Gabriella et al., "Chimeric snRNA molecules carrying antisense sequences against the splice junctions of exon 51 of the dystrophic pre-mRNA induce exon skipping and restoration of a dystrophin synthesis in 48-50 DMD cells," PNAS, Vol. 99(14):9456-9461 (2002)	<input type="checkbox"/>
14	Decision on Appeal, Ex Parte Martin Gleave and Hideaki Miyake, Appeal No. 2005-2447, Appl. No. 09/619,908 (January 31, 2006) (2009 WL 6927761 (Bd.Pat.App.& Interf.), Pages 12, Exhibit Number 1207 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
15	Decision on Request for ReHearing, Ex Parte Roderick John Scott, Appeal No. 2008-004077, Appl. No. 10/058,825 (January 6, 2010) (2010 WL 191079 (Bd.Pat.App. & Interf.),Pages 21, Exhibit Number 1208 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
16	Declaration of Judith C.T. van Deutekom Under 37 C.F.R. §1.132, filed on January 27, 2012, in U.S. Patent Reexamination Control No 90/011,320, regarding U.S. Patent No. 7,534,879, (University of Western Australia Exhibit 2133, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-10).	<input type="checkbox"/>
17	Declaration of Judith van Deutekom, Pages 45, Exhibit Number 1125 filed in interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
18	DELLORUSSO, Christiana et al., "Functional correction of adult mdx mouse muscle using gutted adenoviral vectors expressing full-length dystrophin," PNAS, Vol. 99(20):12979-12984 (2002)	<input type="checkbox"/>
19	Deposition Transcript of Erik J. Sontheimer, Ph.D. of January 21, 2015 (99 pages), Exhibit Number 1215 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
20	Deposition Transcript of Matthew J. A. Wood, M.D. , D. Phil., January 22, 2015, including Errata Sheet, Pages 198, Exhibit Number 1007 filed in Interference 106,013 on February 17, 2015.	<input type="checkbox"/>
21	Deposition Transcript of Matthew J. A. Wood, M.D., D. Phil., Pages 196, Exhibit Number 1122 filed in interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
22	Desalting of Oligonucleotides, Pages 2, Exhibit Number 1132 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>

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23	DIRKSEN, Wessel P. et al., "Mapping the SF2/ASF Binding Sites in the Bovine Growth Hormone Exonic Splicing Enhancer," The Journal of Biological Chemistry, Vol. 275(37):29170-29177 (2000)	<input type="checkbox"/>
24	DOMINSKI, Zbigniew et al., "Identification and Characterization by Antisense Oligonucleotides of Exon and Intron Sequences Required for Splicing," Molecular and Cellular Biology, Vol. 14(11):7445-7454 (1994)	<input type="checkbox"/>
25	DOMINSKI, Zbigniew et al., "Restoration of correct splicing in thalassemic pre-mRNA by antisense oligonucleotides," Proc. Natl. Acad. Sci. USA, Vol. 90:8673-8677 (1993)	<input type="checkbox"/>
26	DORAN, Philip et al., "Proteomic profiling of antisense-induced exon skipping reveals reversal of pathobiochemical abnormalities in dystrophic mdx diaphragm," Proteomics, Vol. 9:671-685, DOI 10.1002/pmic.200800441 (2009)	<input type="checkbox"/>
27	DOUGLAS, Andrew G.L. et al., "Splicing therapy for neuromuscular disease," Molecular and Cellular Neuroscience, Vol. 56:169-185 (2013) (Exhibit Number 2005 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
28	Doyle, Donald F., et al. (2001) "Inhibition of Gene Expression Inside Cells by PeptideNucleic Acids: Effect of mRNA Target Sequence, Mismatched Bases, and PNA Length," Biochemistry 40:53-64, (Exhibit Number 2123 filed in interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
29	Dr. Wood Errata Sheet - 22 Jan 2015, Pages 2, Exhibit Number 1227 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
30	DUNCKLEY, Matthew G. et al., "Modification of splicing in the dystrophin gene in cultured Mdx muscle cells by antisense oligoribonucleotides," Human Molecular Genetics, Vol. 5(1):1083-1090 (1995)	<input type="checkbox"/>
31	DUNCKLEY, Matthew G. et al., "Modulation of Splicing in the DMD Gene by Antisense Oligoribonucleotides," Nucleosides & Nucleotides, Vol. 16(7-9):1665-1668 (1997)	<input type="checkbox"/>
32	ECKSTEIN, F., "Nucleoside Phosphorothioates," Ann. Rev. Biochem., Vol. 54:367-402 (1985) (Exhibit Number 1028 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
33	ELAYADI, Anissa N. et al., "Application of PNA and LNA oligomers to chemotherapy," Current Opinion in Investigational Drugs, Vol. 2(4):558-561 (2001)	<input type="checkbox"/>

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34	Email from Danny Huntington to Interference Trial Section, dated September 21, 2014, Pages 2, Exhibit Number 3001 filed in Interference 106,007, 106,008, and 106,013 on September 26, 2014.	<input type="checkbox"/>
35	Email From Sharon Crane to Interference Trial Section, dated November 13, 2014, Pages 2, Exhibit Number 3002 filed in Interference 106,007, 106,008, and 106,013 on dated November 14, 2014.	<input type="checkbox"/>
36	Emery, A.E. H., "Population frequencies of inherited neuromuscular diseases - a world survey," Neuromuscul Disord 1991;1:19-29.	<input type="checkbox"/>
37	Errata sheet for the January 22, 2015 deposition of Matthew J. A. Wood, M.D., D. PHIL., 2 pages, (Exhibit Number 2128 filed in interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
38	Errata sheet for the March 12, 2015 deposition of Erik J. Sontheimer, Ph.D., (University of Western Australia Exhibit 2149, filed April 3, 2015 in Interferences 106007, 106008, and 106013, page 1).	<input type="checkbox"/>
39	ERRINGTON, Stephen J. et al., "Target selection for antisense oligonucleotide induced exon skipping in the dystrophin gene," The Journal of Gene Medicine, Vol. 5:518-527 (2003)	<input type="checkbox"/>
40	European Office Action for Application No. 09752572.9, 5 pages, dated February 29, 2012	<input type="checkbox"/>
41	European Response, Application No. 10004274.6, 7 pages, dated November 5, 2013 (Exhibit Number 1060 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
42	European Response, Application No. 12198517.0, 7 pages, dated October 21, 2014 (Exhibit Number 2084 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
43	European Response, Application No. 13160338.3, 4 pages, dated June 26, 2014 (Exhibit Number 2085 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
44	European Search Report for Application No. 10004274.6, 12 pages, dated January 2, 2013	<input type="checkbox"/>

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45	European Search Report for Application No. 12162995.0, 11 pages, dated January 15, 2013	<input type="checkbox"/>
46	European Search Report, EP15168694.6, dated July 23, 2015, pages 1-8.	<input type="checkbox"/>
47	Excerpts from Prosecution History of Application No. 13/741,150: Notice of Allowance dated March 16, 2015; List of References cited by Applicant and Considered by Examiner; Notice of Allowance and Fees due dated September 18, 2014; Amendment in Response to Non-Final Office Action dated July 11, 2014, (Academisch Ziekenhuis Leiden Exhibit 1229, filed April 3, 2015 in Interference 106007 and 106008, pages 1-133).	<input type="checkbox"/>
48	Excerpts from Prosecution History of Application No. 13/826,880: Notice of Allowance dated January 26, 2015 and Amendment in Response to Non-Final Office Action dated October 15, 2014, (Academisch Ziekenhuis Leiden Exhibit 1228, filed April 3, 2015 in Interference 106007 and 106008, pages 1-16).	<input type="checkbox"/>
49	Excerpts from Yeo (Ed.), "Systems Biology of RNA Binding Proteins," Adv. Exp. Med. Biol., Chapter 9, 56 pages (2014), (Academisch Ziekenhuis Leiden Exhibit 1232, filed April 3, 2015 in Interference 106007 and 106008, pages 1-56).	<input type="checkbox"/>
50	Excerpts of SEC Form 8-K, dated November 23 2014, for BioMarin Pharmaceutical Inc., (University of Western Australia Exhibit 2129, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-9).	<input type="checkbox"/>

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1	AON PS229 (h53AON1) HPLC Method Report, Pages 3, Exhibit Number 1139 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
2	AON PS229 (h53AON1) Mass Spectrometry Data, Pages 3, Exhibit Number 1142 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
3	AON PS229 (h53AON1) Synthesis Laboratory Notebook Entry, Pages 1, Exhibit Number 1137 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
4	AON PS229L (h53AON229L) Certificate of Analysis, Pages 1, Exhibit Number 1129 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
5	AON PS43 (h51AON1) Certificate of Analysis, Pages 1, Exhibit Number 1134 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
6	AON PS43 (h51AON1) HPLC Chromatogram, Pages 1, Exhibit Number 1131 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
7	AON PS43 (h51AON1) HPLC Method Report, Pages 4, Exhibit Number 1130 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
8	AON PS43 (h51AON1) Mass Spectrometry Data, Pages 3, Exhibit Number 1135 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
9	AON PS43 (h51AON1) UPLC-UV Data, Pages 2, Exhibit Number 1136 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
10	AONs PS1958, PS1959, PS1960, PS1961, PS1962, PS1963, PS1964, PS1965, PS1966, and PS1967 HPLC Method Report, Pages 3, Exhibit Number 1143 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
11	Applicant-Initiated Interview Summary dated April 8, 2013 in U.S. Application Serial No. 13/094,548, (University of Western Australia Exhibit 2144, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-11).	<input type="checkbox"/>

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12	Arechavala-Gomez V, et al., "Immunohistological intensity measurements as a tool to assess sarcolemma-associated protein expression," Neuropathol Appl Neurobiol 2010;36: 265-74.	<input type="checkbox"/>
13	ARECHAVALA-GOMEZA, V. et al., "Comparative Analysis of Antisense Oligonucleotide Sequences for Targeted Skipping of Exon 51 During Dystrophin Pre-mRNA Splicing in Human Muscle," Human Gene Therapy, Vol. 18:798-810 (2007)	<input type="checkbox"/>
14	ARORA, Vikram et al., "c-Myc Antisense Limits Rat Liver Regeneration and Indicates Role for c-Myc in Regulating Cytochrome P-450 3A Activity," The Journal of Pharmacology and Experimental Therapeutics, Vol. 292(3):921-928 (2000)	<input type="checkbox"/>
15	Asetek Danmark A/S v. CMI USA, Inc., 2014 WL 5990699, N.D. Cal. 2014, 8 pages, (Academisch Ziekenhuis Leiden Exhibit 1237, filed May 5, 2015 in Interference 106007 and 106008).	<input type="checkbox"/>
16	ASVADI, Parisa et al., "Expression and functional analysis of recombinant scFv and diabody fragments with specificity for human RhD," Journal of Molecular Recognition, Vol. 15:321-330 (2002)	<input type="checkbox"/>
17	Australian Application No. 2004903474, 36 pages, dated July 22, 2005 (Exhibit Number 1004 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
18	AVI BioPharma, Inc., "Exon 51 Sequence of Dystrophin," Document D19 as filed in Opposition of European Patent EP1619249, filed June 23, 2009, 7 pages	<input type="checkbox"/>
19	AVI BioPharma, The Lancet Published Clinical Trial Data That Demonstrate Statistically Significant and Dose-Dependent Expression of Dystrophin in Duchenne Muscular Dystrophy Patients With AVI BioPharma's Eteplirsen, Press Release, July 25, 2011, pages 1-2.	<input type="checkbox"/>
20	AZL's PCT/NL03/00214 (the as-filed AZL PCT Application) Exhibit No. 1006, filed in Interference No. 106,007, 64 pages, December 23, 2014	<input type="checkbox"/>
21	AZL's U.S. Patent Application No. 14/295,311 and claims, as-filed June 3, 2014 ("the '311 Application") (Exhibit Number 1077 filed in interferences 106008, 106007 on December 23, 2014)	<input type="checkbox"/>
22	Azofeifa J, et al., "X-chromosome methylation in manifesting and healthy carriers of dystrophinopathies: concordance of activation ratios among first degree female relatives and skewed inactivation as cause of the affected phenotypes," Hum Genet 1995;96:167-176.	<input type="checkbox"/>

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23	BEAUCAGE, S.L. et al., "Deoxynucleoside Phosphoramidites - A New Class of Key Intermediates for Deoxypolynucleotide Synthesis," Tetrahedron Letters, Vol. 22(20):1859-1862 (1981)	<input type="checkbox"/>
24	BELLARE, Priya et al., "A role for ubiquitin in the spliceosome assembly pathway," Nature Structural & Molecular Biology, Vol. 15(5):444-451 (2008) (Exhibit Number 1057 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
25	BELLARE, Priya et al., "Ubiquitin binding by a variant Jab1/MPN domain in the essential pre-mRNA splicing factor Prp8p," RNA, Vol. 12:292-302 (2006) (Exhibit Number 1056 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
26	BENNETT, C. Frank et al., "RNA Targeting Therapeutics: Molecular Mechanisms of Antisense Oligonucleotides as a Therapeutic Platform," Annu. Rev. Pharmacol. Toxicol., Vol. 50:259-293 (2010) (Exhibit Number 1025 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
27	BERGE, Stephen M. et al., "Pharmaceutical Salts," Journal of Pharmaceutical Sciences, Vol. 66(1):1-18 (1977)	<input type="checkbox"/>
28	Bestas et al., "Design and Application of Bispecific Splice Switching Oligonucleotides," Nuc. Acid Therap., Vol. 24, No. 1, pp. 13-24 (2014), Exhibit Number 1120 filed in interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
29	BRAASCH, Dwaine A. et al., "Locked nucleic acid (LNA): fine-tuning the recognition of DNA and RNA," Chemistry & Biology, Vol. 8:1-7 (2001) (Exhibit Number 2009 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
30	BRAASCH, Dwaine A. et al., "Novel Antisense and Peptide Nucleic Acid Strategies for Controlling Gene Expression," Biochemistry, Vol. 41(14):4503-4510 (2002) (Exhibit Number 2006 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
31	BREMMER-BOUT, Mattie et al., "Targeted Exon Skipping in Transgenic hDMD Mice: A Model for Direct Preclinical Screening of Human-Specific Antisense Oligonucleotides," Molecular Therapy, Vol. 10(2):232-240 (2004) (Exhibit Number 2024 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
32	Brooke MH, et al., "Clinical investigation in Duchenne dystrophy: 2. Determination of the "power" of therapeutic trials based on the natural history," Muscle Nerve. 1983;6:91-103.	<input type="checkbox"/>
33	BROWN, Susan C. et al., "Dystrophic phenotype induced in vitro by antibody blockade of muscle alpha-dystroglycan-laminin interaction," Journal of Cell Science, Vol. 112:209-216 (1999)	<input type="checkbox"/>

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34	Bushby K, et al. "Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and pharmacological and psychosocial management," Lancet Neurol 2010;9:77-93.	<input type="checkbox"/>
35	Bushby KM, et al., "The clinical, genetic and dystrophin characteristics of Becker muscular dystrophy," II. Correlation of phenotype with genetic and protein abnormalities. J Neurol 1993;240: 105-112.	<input type="checkbox"/>
36	Bushby KM, et al., "The clinical, genetic and dystrophin characteristics of Becker muscular dystrophy," I. Natural history. J Neurol 1993;240:98-104.	<input type="checkbox"/>
37	CANONICO, A.E. et al., "Expression of a CMV Promoter Drive Human alpha-1 Antitrypsin Gene in Cultured Lung Endothelial Cells and in the Lungs of Rabbits," Clinical Research, Vol. 39(2):219A (1991)	<input type="checkbox"/>
38	CIRAK, Sebahattin et al., "Exon skipping and dystrophin restoration in patients with Duchenne muscular dystrophy after systemic phosphorodiamidate morpholino oligomer treatment: an open-label, phase 2, dose-escalation study," Lancet, Vol. 378(9791):595-605 (2011)	<input type="checkbox"/>
39	Claim Chart 11/233,495, Pages 57, Exhibit Number 1216 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
40	Claim Chart 13/550,210, Pages 45, Exhibit Number 1217 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
41	Claim Chart, US 7,807,816, 14 pages (Exhibit Number 1063 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
42	Claim Chart, US 7,960,541, 17 pages (Exhibit Number 1064 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
43	Claim Chart, US 8,455,636, 32 pages (Exhibit Number 1062 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
44	Claim Comparison Chart - Claims 11 and 29 in 13/550,210, Pages 1, Exhibit Number 1226 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>

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45	Claim Comparison Chart 13/550,210 vs 11/233,495, Pages 12, Exhibit Number 1218 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
46	Claim Comparison Chart 13/550,210 vs 12/198,007, Pages 1, Exhibit Number 1219 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
47	Claims from US Application No. 11/233,495, 6 pages, dated September 21, 2005 (Exhibit Number 2068 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
48	Classification Excerpts from USPC System, 21 pages, (Academisch Ziekenhuis Leiden Exhibit 1234, filed May 5, 2015 in Interference 106007 and 106008).	<input type="checkbox"/>
49	COLLINS, C.A. et al., "Duchenne's muscular dystrophy: animal models used to investigate pathogenesis and develop therapeutic strategies," Int. J. Exp. Pathol., Vol. 84(4):165-172 (2003)	<input type="checkbox"/>
50	Confirmation of Dystrophin Exon 48 to 50 Deletion in Cell Line 8036 Laboratory Notebook Entry, Pages 3, Exhibit Number 1167 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>

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1	Yin et al., "Functional Rescue of Dystrophin-deficient mdx Mice by a Chimeric Peptide-PMO," Mol. Therapy, Vol. 18, No. 10, pp. 1822-1829 (October, 2010), Exhibit Number 1117 filed in interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
2	Yokota et al., "Efficacy of Systematic Morpholino Exon-Skipping in Duchenne Dystrophy Dogs," American Neurological Assoc., Vol. 65, No. 6, pp. 667-676 (June, 2009), Exhibit Number 1214 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
3	Zoltek Corp. v. U.S., 95 Fed. Cl. 681 (2011), 23 pages, (Academisch Ziekenhuis Leiden Exhibit 1236, filed May 5, 2015 in Interference 106007 and 106008).	<input type="checkbox"/>
4	International Preliminary Report on Patentability, PCT/US2014/029689, dated September 15, 2015, pages 1-10.	<input type="checkbox"/>

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1	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Notice of Related Proceedings, Patent Interference No. 106,013, 3 pages, dated October 15, 2014 (Doc 11)	<input type="checkbox"/>
2	University of Western Australia v. Academisch Ziekenhuis Leiden, Clean Copy of Claims and Sequences, 5 pages, dated August 5, 2014, Interference No. 106,008, (Exhibit Number 2047 filed in interferences 106,008, 106,013, 106,007 on November 18, 2014)	<input type="checkbox"/>
3	University of Western Australia v. Academisch Ziekenhuis Leiden, Clean Copy of Claims and Sequences, 5 pages, dated July 31, 2014, Interference No. 106,007, (Exhibit Number 2045 filed in interferences 106,008, 106,013, 106,007 on November 18, 2014)	<input type="checkbox"/>
4	University of Western Australia v. Academisch Ziekenhuis Leiden, Clean Copy of Claims and Sequences, 5 pages, dated October 15, 2014., Interference No. 106,013, (Exhibit Number 2050 filed in interferences 106,008, 106,013, 106,007 on November 18, 2014)	<input type="checkbox"/>
5	University of Western Australia v. Academisch Ziekenhuis Leiden, Decision- Motions- 37 CFR§ 41.125(a), filed in Patent Interference No. 106,013, June 22, 2015, pages 1-12 (Doc 192).	<input type="checkbox"/>
6	University of Western Australia v. Academisch Ziekenhuis Leiden, Declaration of Erik Sontheimer dated November 17, 2014, Exhibit 1012 filed in Patent Interference Nos. 106,007 and 106,008, 112 pages, filed November 18, 2014	<input type="checkbox"/>
7	University of Western Australia v. Academisch Ziekenhuis Leiden, Declaration of Interference, Patent Interference No. 106,007, 7 pages, dated July 18, 2014 (Doc 1)	<input type="checkbox"/>
8	University of Western Australia v. Academisch Ziekenhuis Leiden, Declaration of Interference, Patent Interference No. 106,008, 7 pages, dated July 24, 2014 (Doc 1)	<input type="checkbox"/>
9	University of Western Australia v. Academisch Ziekenhuis Leiden, Declaration of Interference, Patent Interference No. 106,013, 8 pages, dated September 29, 2014 (Doc 1)	<input type="checkbox"/>
10	University of Western Australia v. Academisch Ziekenhuis Leiden, Declaration of Matthew J.A. Wood, Patent Interference Nos. 106,007, 106,008 and 106,013, 184 pages, dated November 18, 2014 (Exhibit Number 2081 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
11	University of Western Australia v. Academisch Ziekenhuis Leiden, Joint Stipulation regarding Time Periods 2, 3 and 4, 3 pages, Patent Interference No. 106,013, (Doc 135), dated November 25, 2015.	<input type="checkbox"/>

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /DS/

Application Number # 36203		14213641
Filing Date		2014-03-14
First Named Inventor	Richard K. BESTWICK	
Art Unit	1674	
Examiner Name	D. H. Shin	
Attorney Docket Number	AVN-017	

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

12	University of Western Australia v. Academisch Ziekenhuis Leiden, Joint Stipulation regarding Time Periods 3-4, 4 pages, Patent Interference No. 106,007, (Doc 243), dated January 29, 2015.	<input type="checkbox"/>
13	University of Western Australia v. Academisch Ziekenhuis Leiden, Joint Stipulation regarding Time Periods 3-4, 4 pages, Patent Interference No. 106,008, (Doc 247), dated January 29, 2015.	<input type="checkbox"/>
14	University of Western Australia v. Academisch Ziekenhuis Leiden, Joint Stipulation regarding Time Periods 3-4, 4 pages, Patent Interference No. 106,013, (Doc 137), dated January 29, 2015.	<input type="checkbox"/>
15	University of Western Australia v. Academisch Ziekenhuis Leiden, Joint Stipulation Regarding Time Periods 4-6, 4 pages, Patent Interference No. 106,007, dated March 19, 2015 (Doc 416)	<input type="checkbox"/>
16	University of Western Australia v. Academisch Ziekenhuis Leiden, Joint Stipulation Regarding Time Periods 4-6, 4 pages, Patent Interference No. 106013, (Doc 151), dated March 19, 2015.	<input type="checkbox"/>
17	University of Western Australia v. Academisch Ziekenhuis Leiden, Joint Stipulation Regarding Time Periods 4-6, 4 pages, Patent Interference No.106,008, (Doc 424), dated March 19, 2015.	<input type="checkbox"/>
18	University of Western Australia v. Academisch Ziekenhuis Leiden, Miscellaneous Order under 37 CFR 41.104(a), 4 pages, Patent Interference Nos. 106,007 and 106,008, dated December 15, 2014	<input type="checkbox"/>
19	University of Western Australia v. Academisch Ziekenhuis Leiden, Order - Authorizing Motions, Patent Interference No. 106,007, 3 pages, dated September 26, 2014 (Doc 20)	<input type="checkbox"/>
20	University of Western Australia v. Academisch Ziekenhuis Leiden, Order - Authorizing Motions, Patent Interference No. 106,007, 6 pages, dated September 23, 2014 (Doc 19)	<input type="checkbox"/>
21	University of Western Australia v. Academisch Ziekenhuis Leiden, Order - Authorizing Motions, Patent Interference No. 106,008, 6 pages, dated September 23, 2014 (Doc 18)	<input type="checkbox"/>
22	University of Western Australia v. Academisch Ziekenhuis Leiden, Order - Miscellaneous 37 C.F.R. 41.104(a), 2 pages, Patent Interference Nos. 106,007, 106,008, 106,013, dated November 14, 2014	<input type="checkbox"/>

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**INFORMATION DISCLOSURE
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Application Number	14213641
Filing Date	2014-03-14
First Named Inventor	Richard K. BESTWICK
Art Unit	1674
Examiner Name	D. H. Shin
Attorney Docket Number	AVN-017

23	University of Western Australia v. Academisch Ziekenhuis Leiden, Order to Show Cause- 37 CFR§ 41.104(a), filed in Patent Interference No. 106,013, June 22, 2015, pages 1-3 (Doc 193).	<input type="checkbox"/>
24	University of Western Australia v. Academisch Ziekenhuis Leiden, Redecaration, Patent Interference No. 106,008, 2 pages, dated September 23, 2014 (Doc 19)	<input type="checkbox"/>
25	University of Western Australia v. Academisch Ziekenhuis Leiden, Second Declaration of Matthew J. A. Wood, M.D., D. PHIL., Patent Interference Nos. 106,007 and 106,008, 78 pages, dated February 17, 2015 (Exhibit Number 2116 filed in interferences 106,007 and 106,008, on February 17, 2015.	<input type="checkbox"/>
26	University of Western Australia v. Academisch Ziekenhuis Leiden, Statement Concerning Initial Settlement Discussions, 3 pages, Patent Interference No. 106,013, (Doc 136), dated December 30, 2014.	<input type="checkbox"/>
27	University of Western Australia v. Academisch Ziekenhuis Leiden, Statement Concerning Subsequent Settlement Discussions, 3 pages, Patent Interference No. 106,007, (Doc 242), dated December 30, 2014.	<input type="checkbox"/>
28	University of Western Australia v. Academisch Ziekenhuis Leiden, Statement Concerning Subsequent Settlement Discussions, 3 pages, Patent Interference No. 106,008, (Doc 246), dated December 30, 2014.	<input type="checkbox"/>
29	University of Western Australia v. Academisch Ziekenhuis Leiden, Statement Concerning Subsequent Settlement Discussions, filed in Patent Interference No. 106,013, August 24, 2015, pages 1-3 (Doc 195).	<input type="checkbox"/>
30	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Response to Order to Show Cause, filed in Patent Interference No. 106,013, July 20, 2015, pages 1-28 (Doc 194).	<input type="checkbox"/>
31	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Exhibit List as of April 10, 2015, filed in Patent Interference No. 106,007, April 10, 2015, pages 1-10 (Doc 456).	<input type="checkbox"/>
32	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Exhibit List as of April 10, 2015, filed in Patent Interference No. 106,008, April 10, 2015, pages 1-10 (Doc 464).	<input type="checkbox"/>
33	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Exhibit List as of April 3, 2015, filed in Interference 106007, April 3, 2015, pages 1-10 (Doc 431).	<input type="checkbox"/>

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /DS/

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	14213641
Filing Date	2014-03-14
First Named Inventor	Richard K. BESTWICK
Art Unit	1674
Examiner Name	D. H. Shin
Attorney Docket Number	AVN-017

34	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Exhibit List as of April 3, 2015, filed in Interference 106008, April 3, 2015, pages 1-10 (Doc 439).	<input type="checkbox"/>
35	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Exhibit List as of April 3, 2015, filed in Interference 106013, April 3, 2015, pages 1-10 (Doc 153).	<input type="checkbox"/>
36	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Miscellaneous Motion 4 (to exclude evidence), filed in Patent Interference No. 106,007, April 10, 2015, pages 1-21 (Doc 455).	<input type="checkbox"/>
37	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Miscellaneous Motion 4 (to exclude evidence), filed in Patent Interference No. 106,008, April 10, 2015, pages 1-21 (Doc 463).	<input type="checkbox"/>
38	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Opposition 1 (Regarding Patentability Under 35 U.S.C. § 102/103), 38 pages, Patent Interference No. 106,007, (Doc 393), dated February 17, 2015	<input type="checkbox"/>
39	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Opposition 1 (Regarding Patentability Under 35 U.S.C. § 102/103), 39 pages, Patent Interference No. 106,008, (Doc 402), dated February 17, 2015	<input type="checkbox"/>
40	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Opposition 2 (To Retain UWA's Benefit of AU 2004903474), 31 pages, Patent Interference No. 106,008, (Doc 403), dated February 17, 2015	<input type="checkbox"/>
41	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Opposition 2 (To Retain UWA's Benefit of AU 2004903474), 37 pages, Patent Interference No. 106,007, (Doc 394), dated February 17, 2015	<input type="checkbox"/>
42	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Opposition 3 (Regarding Patentability Under 35 U.S.C. § 101), 22 pages, Patent Interference No. 106,007, (Doc 395), dated February 17, 2015	<input type="checkbox"/>
43	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Opposition 3 (Regarding Patentability Under 35 U.S.C. § 101), 22 pages, Patent Interference No. 106,008, (Doc 404), dated February 17, 2015	<input type="checkbox"/>
44	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Opposition 4 (To deny entry of AZL's Proposed New Claims 104 and 105), 36 pages, Patent Interference No. 106,007, (Doc 397), dated February 17, 2015	<input type="checkbox"/>

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /DS/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)

Application Number	14213641
Filing Date	2014-03-14
First Named Inventor	Richard K. BESTWICK
Art Unit	1674
Examiner Name	D. H. Shin
Attorney Docket Number	AVN-017

45	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Opposition 4 (To deny entry of AZL's Proposed New Claims 30 and 31), 36 pages, Patent Interference No. 106,008, (Doc 405), dated February 17, 2015	<input type="checkbox"/>
46	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Reply 1 (to AZL Opposition 1), filed April 3, 2015 in Interference 106007, pages 1-28 (Doc 428).	<input type="checkbox"/>
47	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Reply 1 (to AZL Opposition 1), filed April 3, 2015 in Interference 106008, pages 1-28, (Doc 436).	<input type="checkbox"/>
48	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Reply 1 (to Maintain the Interference) filed April 3, 2015 in Interference 106013, pages 1-17 (Doc 152).	<input type="checkbox"/>
49	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Reply 2 (to AZL Opposition 2) filed April 3, 2015 in Interference 106007, pages 1-22 (Doc 429)	<input type="checkbox"/>
50	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Reply 2 (to AZL Opposition 2) filed April 3, 2015 in Interference 106008, pages 1-22 (Doc 437).	<input type="checkbox"/>

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		14213641	
	Filing Date		2014-03-14	
	First Named Inventor	Richard K. BESTWICK		
	Art Unit	1674		
	Examiner Name	D. H. Shin		
	Attorney Docket Number	AVN-017		

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Application Number
36208

14213641

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Filing Date	2014-03-14
First Named Inventor	Richard K. BESTWICK
Art Unit	1674
Examiner Name	D. H. Shin
Attorney Docket Number	AVN-017

1	Exon 51 Internal Sequence Schematic, Pages 1, Exhibit Number 1224 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
2	Exon 53 Internal Sequence Schematic, Pages 1, Exhibit Number 1225 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
3	Fairclough et al., "Therapy for Duchenne muscular dystrophy: renewed optimism from genetic approaches," Nature Reviews, Vol. 14, pp. 373-378 (June, 2013), Exhibit Number 1112 filed in interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
4	FALL, Abbie M. et al., "Induction of revertant fibres in the mdx mouse using antisense oligonucleotides," Genetic Vaccines and Therapy, Vol. 4:3, doi:10.1186/1479-0556-4-3, 12 pages (2006)	<input type="checkbox"/>
5	Federal Register, Vol. 58, No. 183, pp. 49432-49434, September 23, 1993 (6 pages); [Cited as: 58 FR 49432-01, 1993 WL 371451 (F.R.)], Exhibit Number 1221 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
6	Federal Register, Vol. 69, No. 155, pp. 49960-50020 dated August 12, 2004 (62 pages), Exhibit Number 1220 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
7	File Excerpt from AZL U.S. Patent Application 11/233,495: Amendment After Non-Final Office Action, as-filed November 1, 2010 (Exhibit Number 1085 filed in interferences 106008, 106007 on December 23, 2014)	<input type="checkbox"/>
8	File Excerpt from AZL U.S. Patent Application 11/233,495: Claims examined in Non-Final Office Action, dated December 1, 2008 (Exhibit Number 1079 filed in interferences 106008, 106007 on December 23, 2014)	<input type="checkbox"/>
9	File Excerpt from AZL U.S. Patent Application 11/233,495: Final Office Action dated August 31, 2010 (Exhibit Number 1086 filed in interferences 106008, 106007 on December 23, 2014)	<input type="checkbox"/>
10	File Excerpt from U.S. Patent Application 11/233,495: Non-Final Office Action dated December 1, 2008 and Final Office Action dated June 25, 2009 (Exhibit Number 1078 filed in interferences 106008, 106007 on December 23, 2014)	<input type="checkbox"/>
11	File Excerpt from U.S. Patent Application No. 12/198,007: AZL's Preliminary Amendment and Response, as-filed November 7, 2008 (Exhibit Number 1075 filed in interferences 106008, 106007 on December 23, 2014)	<input type="checkbox"/>

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Application Number
36209

14213641

**INFORMATION DISCLOSURE
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(Not for submission under 37 CFR 1.99)

Filing Date

2014-03-14

First Named Inventor

Richard K. BESTWICK

Art Unit

1674

Examiner Name

D. H. Shin

Attorney Docket Number

AVN-017

12	File Excerpt from U.S. Patent Application No. 12/976,381: AZL's First Preliminary Amendment, as-filed December 22, 2010 (Exhibit Number 1076 filed in interferences 106008, 106007 on December 23, 2014)	<input type="checkbox"/>
13	File Excerpts from Prosecution History of U.S. Patent Application No. 13/270,992 ("UWA's U.S. Patent 8,486,907), Pages 122, Exhibit Number 1006 filed in Interference 106,013 on February 17, 2015.	<input type="checkbox"/>
14	File Excerpts from U.S. Patent Application No. 11/233,495: Response to Non- Final Office Action, as filed July 26, 2011 (14 pages), Exhibit Number 1222 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
15	File Excerpts from U.S. Patent Application No. 13/270,992 ("UWA's U.S. Patent 8,486,907): NFOA, dated 7/30/2012; Applicant-Initiated Interview Summary, dated 11/8/2012; Amendment, as filed January 30, 2013; NOA, dated 4/4/2013, Exhibit Number 1118 (122 pages) filed in interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
16	Flanagan, W. Michael, et al., "A cytosine analog that confers enhanced potency to antisense oligonucleotides," Proc. Nat'l Acad. Sci. USA, Vol. 96, pp. 3513-3518 (March, 1999), Exhibit Number 1211 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
17	FLANIGAN, Kevin M. et al., "Pharmacokinetics and safety of single doses of drisapersen in non-ambulant subjects with Duchenne muscular dystrophy: Results of a double-blind randomized clinical trial," Neuromuscular Disorders, Vol. 24:16-24 (2014) (Exhibit Number 2038 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
18	Flanigan, Kevin M., et al. (2003) "Rapid Direct Sequence Analysis of the Dystrophin Gene," Am. J. Hum. Genet. 72:931-939, dated February 17, 2015 (Exhibit Number 2120 filed in interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
19	Fletcher S., et al., "Morpholino oligomer-mediated exon skipping averts the onset of dystrophic pathology in the mdx mouse. Mol Ther 2007;15:1587-1592.	<input type="checkbox"/>
20	FLETCHER, Sue et al., "Dystrophin Isoform Induction In Vivo by Antisense-mediated Alternative Splicing," Molecular Therapy, Vol. 18(6):1218-1223 (2010)	<input type="checkbox"/>
21	FLETCHER, Sue et al., "Targeted Exon Skipping to Address 'Leaky' Mutations in the Dystrophin Gene," Molecular Therapy-Nucleic Acids, Vol. 1, e48, doi:10.1038/mtna.2012.40, 11 pages (2012)	<input type="checkbox"/>
22	FLETCHER, Susan et al., "Dystrophin expression in the mdx mouse after localised and systemic administration of a morpholino antisense oligonucleotide," J. Gene Med., Vol. 8:207-216 (2006)	<input type="checkbox"/>

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /DS/

Application Number
36210

14213641

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Filing Date	2014-03-14
First Named Inventor	Richard K. BESTWICK
Art Unit	1674
Examiner Name	D. H. Shin
Attorney Docket Number	AVN-017

23	FLETCHER, Susan et al., "Gene therapy and molecular approaches to the treatment of hereditary muscular disorders," Curr. Opin. Neurol., Vol. 13:553-560 (2000)	<input type="checkbox"/>
24	FOSTER, Helen et al., "Genetic Therapeutic Approaches for Duchenne Muscular Dystrophy," Human Gene Therapy, Vol. 23:676-687 (2012)	<input type="checkbox"/>
25	Fourth Declaration of Erik Sontheimer, Ph.D. (Pursuant to Bd.R. 41.155(b)(2) and SO ¶¶ 155.1.3 and 155.1.4), dated March 9, 2015, (University of Western Australia Exhibit 2138, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-4).	<input type="checkbox"/>
26	FRAGALL, Clayton T. et al., "Mismatched single stranded antisense oligonucleotides can induce efficient dystrophin splice switching," BMC Medical Genetics, Vol. 12:141, 8 pages (2011) (Exhibit Number 2019 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
27	FRALEY, Robert et al., "New generation liposomes: the engineering of an efficient vehicle for intracellular delivery of nucleic acids," Trends Biochem., Vol. 6:77-80 (1981)	<input type="checkbox"/>
28	FRAZIER, Kendall S. et al., "Species-specific Inflammatory Responses as a Primary Component for the Development of Glomerular Lesions in Mice and Monkeys Following Chronic Administration of a Second-generation Antisense Oligonucleotide," Toxicologica Pathology, 13 pages (2013)	<input type="checkbox"/>
29	FRIEDMANN, Theodore, "Progress Toward Human Gene Therapy," Science, Vol. 244(4910):1275-1281 (1989)	<input type="checkbox"/>
30	GEBSKI, Bianca L. et al., "Morpholino antisense oligonucleotide induced dystrophin exon 23 skipping in mdx mouse muscle," Human Molecular Genetics, Vol. 12(15):1801-1811 (2003)	<input type="checkbox"/>
31	Generic Method for Average Mass Determination Using LC-UV-MS in the Negative Mode, Pages 15, Exhibit Number 1145 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
32	Generic UPLC Purity Method for Oligonucleotides (19- to 25-mers), Pages 18, Exhibit Number 1156 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
33	GENNARO, Alfonso R., (ed.), Remington's Pharmaceutical Sciences, 18th Edition, Mack Publishing, Co., Easton PA, 2020 pages (1990)	<input type="checkbox"/>

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**INFORMATION DISCLOSURE
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Application Number	14213641
Filing Date	2014-03-14
First Named Inventor	Richard K. BESTWICK
Art Unit	1674
Examiner Name	D. H. Shin
Attorney Docket Number	AVN-017

34	GILES, Richard V. et al., "Antisense Morpholino Oligonucleotide Analog Induces Missplicing of C-myc mRNA," Antisense & Nucleic Acid Drug Development, Vol. 9:213-220 (1999)	<input type="checkbox"/>
35	GlaxoSmithKline Press Release, Issued in London, UK, dated June 27, 2013 (5 pages), Exhibit Number 1202 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
36	GlaxoSmithKline, "GSK and Prosensa announce start of Phase III study of investigational Duchenne Muscular Dystrophy medication," press release, 6 pages, dated January 19, 2011 (Exhibit Number 2060 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
37	GlaxoSmithKline, "Prosensa regains rights to drisapersen from GSK and retains rights to all other programmes for the treatment of Duchenne muscular dystrophy (DMD), press release, 4 pages, dated January 13, 2014 (Exhibit 2040 in Interferences 106007, 106008, and 106013 on November 18, 2014).	<input type="checkbox"/>
38	GOEMANS, Nathalie M. et al., "Systemic Administration of PRO051 in Duchenne's Muscular Dystrophy," The New England Journal of Medicine, Vol. 364:1513-1522 (2011) (Exhibit Number 2036 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
39	GORDON, Peter M. et al., "Metal ion catalysis during the exon-ligation step of nuclear pre-mRNA splicing: Extending the parallels between the spliceosome and group II introns," RNA, Vol. 6:199-205 (2000) (Exhibit Number 1055 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
40	Gordon, Peter M., et al., "Kinetic Characterization of the Second Step of Group II Intron Splicing: Role of Metal Ions and the Cleavage Site 2'-OH in Catalysis," Biochemistry, Vol. 39, pp. 12939-12952 (2000), Exhibit Number 1188 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
41	GOYENVALLE, Aurelie et al., "Prevention of Dystrophic Pathology in Severely Affected Dystrophin/Utrophin-deficient Mice by Morpholino-oligomer-mediated Exon-skipping," Molecular Therapy, Vol. 18(1):198-205 (2010)	<input type="checkbox"/>
42	HAMMOND, Suzan M. et al., "Correlating In Vitro Splice Switching Activity With Systemic In Vivo Delivery Using Novel ZEN-modified Oligonucleotides," Molecular Therapy - Nucleic Acids, Vol. 3:1, 11 pages (2014) (Exhibit Number 2011 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
43	Hammond, Suzan M., et al., "Genetic therapies for RNA mis-splicing diseases," Cell, Vol.27, No. 5, pp. 196-205 (May, 2011), Exhibit Number 1113 filed in interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
44	Hammond, Suzan M., et al., "PRO-051, an antisense oligonucleotide for the potential treatment of Duchenne muscular dystrophy," Curr. Opinion Mol. Therap., Vol. 12, No. 4, pp. 478-486 (2010), Exhibit Number 1121 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /DS/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Filing Date	2014-03-14
First Named Inventor	Richard K. BESTWICK
Art Unit	1674
Examiner Name	D. H. Shin
Attorney Docket Number	AVN-017

45	HARDING, PL et al., "The Influence of Antisense Oligonucleotide Length on Dystrophin Exon Skipping," Molecular Therapy, Vol. 15(1):157-166 (2007) (Exhibit Number 1030 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
46	HAREL-BELLAN, Annick et al., "Specific Inhibition of c-myc Protein Biosynthesis Using an Antisense Synthetic Deoxy-Oligonucleotide in Human T Lymphocytes," The Journal of Immunology, Vol. 140(7):2431-2435 (1988)	<input type="checkbox"/>
47	Havenga, M.J.E., et al., "Exploiting the Natural Diversity in Adenovirus Tropism for Therapy and Prevention of Disease," J. Virol., Vol. 76, No. 9, pp. 4612-4620 (May, 2002), Exhibit Number 1123 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
48	HEASMAN, Janet, "Morpholino Oligos: Making Sense of Antisense?" Developmental Biology, Vol. 243:209-214 (2002)	<input type="checkbox"/>
49	HEEMSKERK, Hans A. et al., "In vivo comparison of 2'-O-methyl phosphorothioate and morpholino antisense oligonucleotides for Duchenne muscular dystrophy exon skipping," The Journal of Gene Medicine, Vol. 11:257-266 (2009) (Exhibit Number 2020 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
50	HEID, Christian A. et al., "Real Time Quantitative PCR," Genome Research, Vol. 6:986-994 (1996) (Exhibit Number 1061 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>

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	Filing Date		2014-03-14
	First Named Inventor	Richard K. BESTWICK	
	Art Unit	1674	
	Examiner Name	D. H. Shin	
	Attorney Docket Number	AVN-017	

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	1	9018368		2015-04-28	Wilton et al.	
	2	9024007		2015-05-05	Wilton et al.	
	3	9035040		2015-05-19	Wilton et al.	

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	1	20120289457	A1	2012-11-15	Hanson	
	2	20120065169	A1	2012-03-15	Hanson et al.	
	3	20130116310	A1	2013-05-09	Wilton et al.	

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30214

14213641

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4	20130217755	A1	2013-08-22	WILTON et al.	
5	20130253033	A1	2013-09-26	WILTON et al.	
6	20130253180	A1	2013-09-26	WILTON et al.	
7	20130274313	A1	2013-10-17	WILTON et al.	
8	20130331438	A1	2013-12-12	WILTON et al.	
9	20140080898	A1	2014-03-20	Wilton et al.	
10	20140094500	A1	2014-04-03	SAZANI et al.	
11	20140155587	A1	2014-06-05	WILTON et al.	
12	20140243515	A1	2014-08-28	WILTON et al.	
13	20140243516	A1	2014-08-28	WILTON et al.	
14	20140315862	A1	2014-10-23	Kaye	

Application Number
30215

14213641

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15	20140315977	A1	2014-10-23	BESTWICK et al.	
16	20140323544	A1	2014-10-30	BESTWICK et al.	
17	20140329762	A1	2014-11-06	KAYE	
18	20140329881	A1	2014-11-06	Bestwick et al.	
19	20140350067	A1	2014-11-27	Wilton et al.	
20	20150152415	A1	2015-06-04	SAZANI et al.	

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	1	2014/144978	WO	A2	2014-09-18	Sarepta Therapeutics, Inc		<input type="checkbox"/>

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1	"Efficacy Study of AVI-4658 to Induce Dystrophin Expression in Selected Duchenne Muscular Dystrophy Patients" ClinicalTrials.gov dated January 22, 2013	<input type="checkbox"/>
2	"Efficacy Study of AVI-4658 to Induce Dystrophin Expression in Selected Duchenne Muscular Dystrophy Patients," Clinical Trial Identifier No. NCT01396239, ClinicalTrials.gov, dated July, 15, 2011, page 1-4.	<input type="checkbox"/>
3	"Eteplirsen - Inhibitor of Dystrophin Expression - Treatment of Duchenne Muscular Dystrophy", Drugs of the Future, Vol.38(1):13-17 (2013)	<input type="checkbox"/>
4	2nd Expert Declaration of Dr. Erik Sontheimer ("2nd S Decl.") (Exhibit Number 1067 filed in interferences 106008, 106007 on December 23, 2014)	<input type="checkbox"/>
5	3rd Declaration of Erik J. Sontheimer, Ph.D. ("3rd S. Decl."), Pages 123, Exhibit Number 1186 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
6	A Comparative Study on AONs between 20 and 50 Nucleotides Designed to Induce the Skipping of Exon 53 from the Dystrophin Pre-mRNA, Pages 6, Exhibit Number 1128 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
7	A Comparative Study on AONs Between 20 and 50 Nucleotides Designed to Induce the Skipping of Exon 51 from the Dystrophin Pre-mRNA, Pages 6, Exhibit Number 1127 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
8	Aartsma-Rus A, et al. "Theoretic applicability of antisense-mediated exon skipping for Duchenne muscular dystrophy mutations," Hum Mutat 2009;30:293-99.	<input type="checkbox"/>
9	Aartsma-Rus et al., "Antisense-induced exon skipping for duplications in Duchenne muscular dystrophy," BMC Medical Genetics 8:43 (2007), (University of Western Australia Exhibit 2135, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-9.)	<input type="checkbox"/>
10	AARTSMA-RUS, Annemieke et al., "194th ENMC international workshop. 3rd ENMC workshop on exon skipping: Towards clinical application of antisense-mediated exon skipping for Duchenne muscular dystrophy 8-10 December 2012, Naarden, The Netherlands," Neuromuscular Disorders, Vol. 23:934-944 (2013)	<input type="checkbox"/>
11	AARTSMA-RUS, Annemieke et al., "Antisense-Induced Multiexon Skipping for Duchenne Muscular Dystrophy Makes More Sense," Am. J. Hum. Genet., Vol. 74:83-92 (2004)	<input type="checkbox"/>

**INFORMATION DISCLOSURE
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12	AARTSMA-RUS, Annemieke et al., "Functional Analysis of 114 Exon-Internal AONs for Targeted DMD Exon Skipping: Indication for Steric Hindrance of SR Protein Binding Sites," Oligonucleotides, Vol. 15:284-297 (2005) (Exhibit Number 2016 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
13	AARTSMA-RUS, Annemieke et al., "Guidelines for Antisense Oligonucleotide Design and Insight Into Splice-modulating Mechanisms," Molecular Therapy, Vol. 17(3):548-553 (2009) (Exhibit Number 2014 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
14	AARTSMA-RUS, Annemieke et al., "Targeted exon skipping as a potential gene correction therapy for Duchenne muscular dystrophy," Neuromuscular Disorders, Vol. 12:S71-S77 (2002)	<input type="checkbox"/>
15	AARTSMA-RUS, Annemieke et al., "Therapeutic antisense-induced exon skipping in cultured muscle cells from six different DMD patients," Human Molecular Genetics, Vol. 12(8):907-914 (2003)	<input type="checkbox"/>
16	ABBS, Stephen et al., "A convenient multiplex PCR system for the detection of dystrophin gene deletions: a comparative analysis with cDNA hybridisation shows mistypings by both methods," J. Med. Genet., Vol. 28:304-311 (1991)	<input type="checkbox"/>
17	Abes, S. et al., "Efficient Splicing Correction by PNA Conjugation to an R6-Penetratin Delivery Peptide", Nucleic Acids Research Vol.35(13):4495-4502 (2007)	<input type="checkbox"/>
18	AGRAWAL, Sudhir et al., "GEM 91 - An Antisense Oligonucleotide Phosphorothioate as a Therapeutic Agent for AIDS," Antisense Research and Development, Vol. 2:261-266 (1992)	<input type="checkbox"/>
19	AGRAWAL, Sudhir et al., "Oligodeoxynucleoside phosphoramidates and phosphorothioates as inhibitors of human immunodeficiency virus," Proc. Natl. Acad. Sci. USA, Vol. 85:7079-7083 (1988)	<input type="checkbox"/>
20	Ahmad A, et al., "Mdx mice inducibly expressing dystrophin provide insights into the potential of gene therapy for Duchenne muscular dystrophy," Hum Mol Genet 2000;9:2507-2515.	<input type="checkbox"/>
21	AKHTAR, Saghir et al., "Cellular uptake and intracellular fate of antisense oligonucleotides," Trends in Cell Biology, Vol. 2:139-144 (1992)	<input type="checkbox"/>
22	AKHTAR, Saghir, "Delivery Strategies for Antisense Oligonucleotide Therapeutics," CRC Press, Inc., Boca Raton, FL, 160 pages (1995)	<input type="checkbox"/>

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30218

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23	Alignments of Dystrophin mRNA and Oligonucleotides, 6 pages, submitted to the Patent Trial and Appeal Board in interference No. 106008, dated November 18, 2014 (Exhibit Number 1054 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
24	ALTER, Julia et al., "Systemic delivery of morpholino oligonucleotide restores dystrophin expression bodywide and improves dystrophic pathology," Nature Medicine, Vol. 12(2):175-177 (2006)	<input type="checkbox"/>
25	Amendment under 37 CFR 1.312 for Application No. 14/248,279, 5 pages, dated September 19, 2014 (Exhibit Number 2053 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
26	Analysis of Second PCR Product by Gel Electrophoresis, Pages 1, Exhibit Number 1182 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
27	ANDERSON, W. French, "Human Gene Therapy," Science, Vol. 256:808-813 (1992)	<input type="checkbox"/>
28	Annotated scenario introduced and referred to during March 12, 2015 deposition of Erik J. Sontheimer, Ph.D., (University of Western Australia Exhibit 2139, filed April 3, 2015 in Interferences 106007, 106008, and 106013, page 1.)	<input type="checkbox"/>
29	ANTHONY, Karen et al., "Dystrophin quantification: Biological and Translational Research Implications," Neurology, Vol. 83:1-8 (2014) (Exhibit Number 2028 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
30	AON PS1958 Mass Spectrometry Data, Pages 7, Exhibit Number 1146 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
31	AON PS1958 UPLC Data, Pages 2, Exhibit Number 1157 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
32	AON PS1959 Mass Spectrometry Data, Pages 5, Exhibit Number 1147 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
33	AON PS1959 UPLC Data, Pages 2, Exhibit Number 1158 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>

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36219

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Richard K. BESTWICK

Art Unit

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34	AON PS1960 Mass Spectrometry Data, Pages 8, Exhibit Number 1148 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
35	AON PS1960 UPLC Data, Pages 2, Exhibit Number 1159 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
36	AON PS1961 Mass Spectrometry Data, Pages 5, Exhibit Number 1149 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
37	AON PS1961 UPLC Data, Pages 2, Exhibit Number 1160 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
38	AON PS1962 Mass Spectrometry Data, Pages 7, Exhibit Number 1150 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
39	AON PS1962 UPLC Data, Pages 2, Exhibit Number 1161 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
40	AON PS1963 Mass Spectrometry Data, Pages 10, Exhibit Number 1151 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
41	AON PS1963 UPLC Data, Pages 2, Exhibit Number 1162 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
42	AON PS1964 Mass Spectrometry Data, Pages 13, Exhibit Number 1152 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
43	AON PS1964 UPLC Data, Pages 2, Exhibit Number 1163 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
44	AON PS1965 Mass Spectrometry Data, Pages 9, Exhibit Number 1153 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>

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36220

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45	AON PS1965 UPLC Data, Pages 2, Exhibit Number 1164 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
46	AON PS1966 Mass Spectrometry Data, Pages 8, Exhibit Number 1154 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
47	AON PS1966 UPLC Data, Pages 2, Exhibit Number 1165 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
48	AON PS1967 Mass Spectrometry Data, Pages 7, Exhibit Number 1155 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
49	AON PS1967 UPLC Data, Pages 2, Exhibit Number 1166 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
50	AON PS229 (h53AON1) HPLC Chromatograph Pages 2, Exhibit Number 1140 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>

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1	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Opposition 1 (35 U.S.C. § 112(a)), 83 pages, Patent Interference No. 106,008, (Doc 400), dated February 17, 2015	<input type="checkbox"/>
2	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Opposition 1 (35 U.S.C. § 112(a)), 93 pages, Patent Interference No. 106,007, (Doc 392), dated February 17, 2015	<input type="checkbox"/>
3	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Opposition 1 (Standing Order ¶ 203.1 and 37 C.F.R. § 41.202(a) and (e)), 20 pages, Patent Interference No. 106,013, (Doc 148), dated February 17, 2015	<input type="checkbox"/>
4	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Opposition 2 (Indefiniteness), 31 pages, Patent Interference No. 106,007, (Doc 396), dated February 17, 2015	<input type="checkbox"/>
5	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Opposition 2 (Indefiniteness), 32 pages, Patent Interference No. 106,008, (Doc 401), dated February 17, 2015	<input type="checkbox"/>
6	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Opposition 3 (35 U.S.C. §135(b)), 44 pages, Patent Interference No. 106,008, (Doc 397), dated February 17, 2015	<input type="checkbox"/>
7	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Opposition 3 (Standing Order § 203.1 and 37 C.F.R. § 41.202(a) and (e)), 20 pages, Patent Interference No. 106,007, (Doc 389), dated February 17, 2015.	<input type="checkbox"/>
8	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 1 (For Judgment that UWA's Claims are Unpatentable Under 35 U.S.C. §§ 102 and 103), dated April 3, 2015, filed in Patent Interference No. 106008, pages 1-17 (Doc 431).	<input type="checkbox"/>
9	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 1 (For Judgment that UWA's Claims are Unpatentable Under 35 U.S.C. §§ 102 and 103), dated April 3, 2015, filed in Patent Interference No. 106007, pages 1-17 (Doc 424).	<input type="checkbox"/>
10	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 2 (To Deny the Benefit of AU 2004903474), dated April 3, 2015, filed in Patent Interference No. 106007, pages 1-11(Doc 425).	<input type="checkbox"/>
11	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 2 (To Deny the Benefit of AU 2004903474), dated April 3, 2015, filed in Patent Interference No. 106008, pages 1-12 (Doc 432).	<input type="checkbox"/>

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12	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 3 (For Judgment of Unpatentability based on Myriad) dated April 3, 2015, filed in Patent Interference No. 106007, pages 1-12 (Doc 426).	<input type="checkbox"/>
13	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 3 (For Judgment of Unpatentability based on Myriad) dated April 3, 2015, filed in Patent Interference No. 106008, pages 1-13 (Doc 433).	<input type="checkbox"/>
14	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 4 (In Support of Responsive Motion 4 to Add Two New Claims) dated April 3, 2015, filed in Patent Interference No. 106007, pages 1-17 (Doc 427).	<input type="checkbox"/>
15	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 4 (In Support of Responsive Motion 4 to Add Two New Claims) dated April 3, 2015, filed in Patent Interference No. 106008, pages 1-17 (Doc 434).	<input type="checkbox"/>
16	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Request For Oral Argument, filed in Patent Interference No. 106,007, April 10, 2015, pages 1-3 (Doc 454).	<input type="checkbox"/>
17	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Request For Oral Argument, filed in Patent Interference No. 106,008, April 10, 2015, pages 1-3 (Doc 462).	<input type="checkbox"/>
18	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Responsive Motion 4 (To Add Two New Claims), 57 pages, Patent Interference No. 106,008, (Doc 245), dated December 23, 2014.	<input type="checkbox"/>
19	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Responsive Motion 4 (To Add Two New Claims), 65 pages, Patent Interference No. 106,007, (Doc 241), dated December 23, 2014.	<input type="checkbox"/>
20	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Statement Regarding Oral Argument, filed in Patent Interference No. 106,013, April 10, 2015, pages 1-3 (Doc 189).	<input type="checkbox"/>
21	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden's List of Exhibits as of May 5, 2015, filed in Patent Interference No. 106,007, May 5, 2015, pages 1-18 (Doc 466).	<input type="checkbox"/>
22	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden's List of Exhibits as of May 5, 2015, filed in Patent Interference No. 106,008, May 5, 2015, pages 1-18 (Doc 474).	<input type="checkbox"/>

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Filing Date	2014-03-14
First Named Inventor	Richard K. BESTWICK
Art Unit	1674
Examiner Name	D. H. Shin
Attorney Docket Number	AVN-017

23	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden's Opposition 4 (To Not Exclude Evidence), filed in Patent Interference No. 106,007, May 5, 2015, pages 1-22 (Doc 465).	<input type="checkbox"/>
24	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden's Opposition 4 (To Not Exclude Evidence), filed in Patent Interference No. 106,008, May 5, 2015, pages 1-21 (Doc 473).	<input type="checkbox"/>
25	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden's Second Supplemental Notice of Real Party in Interest, filed in Patent Interference No. 106,007, May 28, 2015, pages 1-3, (Doc 468)	<input type="checkbox"/>
26	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden's Second Supplemental Notice of Real Party in Interest, filed in Patent Interference No. 106,008, May 28, 2015, pages 1-3, (Doc 476)	<input type="checkbox"/>
27	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden's Second Supplemental Notice of Real Party in Interest, filed in Patent Interference No. 106013, May 28, 2015, pages 1-3, (Doc 191)	<input type="checkbox"/>
28	University of Western Australia v. Academisch Ziekenhuis Leiden, ACADEMISH ZIEKENHUIS LEIDEN SUPPLEMENTAL NOTICE OF REAL PARTY IN INTEREST, Pages 3, DOC 149, Patent Interference No. 106,013 dated February 23, 2015.	<input type="checkbox"/>
29	University of Western Australia v. Academisch Ziekenhuis Leiden, ACADEMISH ZIEKENHUIS LEIDEN SUPPLEMENTAL NOTICE OF REAL PARTY IN INTEREST, Pages 3, Doc 413, Patent Interference No. 106,007 dated February 23, 2015.	<input type="checkbox"/>
30	University of Western Australia v. Academisch Ziekenhuis Leiden, ACADEMISH ZIEKENHUIS LEIDEN SUPPLEMENTAL NOTICE OF REAL PARTY IN INTEREST, Pages 3, Doc 421, Patent Interference No. 106,0008 dated February 23, 2015.	<input type="checkbox"/>
31	University of Western Australia v. Academisch Ziekenhuis Leiden, Amendment and Response, US Application No. 11/233,495, Filed 1/22/2014, 8 pages, (Exhibit Number 2117 filed in interferences 106,007 and 106, 008, on February 17, 2015.	<input type="checkbox"/>
32	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Annotated Copy of Claims, Patent Interference No. 106,007, 15 pages, dated August 15, 2014 (Doc 15)	<input type="checkbox"/>
33	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Annotated Copy of Claims, Patent Interference No. 106,008, 14 pages, dated August 21, 2014 (Doc 14)	<input type="checkbox"/>

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STATEMENT BY APPLICANT**
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Application Number	14213641
Filing Date	2014-03-14
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Attorney Docket Number	AVN-017

34	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Annotated Copy of Claims, Patent Interference No. 106,013, 14 pages, dated October 27, 2014 (Doc 16)	<input type="checkbox"/>
35	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Clean Copy of Claims and Sequence, filed in Patent Interference No. 106,013, 5 pages, dated October 15, 2014 (Doc 12)	<input type="checkbox"/>
36	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Corrected Notice of Related Proceedings, Patent Interference No. 106,007, 3 pages, dated August 1, 2014 (Doc 13)	<input type="checkbox"/>
37	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Exhibit List, 10 pages, Patent Interference No. 106,007 dated December 23, 2014 (Doc 240)	<input type="checkbox"/>
38	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Exhibit List, 10 pages, Patent Interference No. 106,008, dated December 23, 2014 (Doc 244)	<input type="checkbox"/>
39	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL List of Exhibits, 9 pages, Patent Interference No. 106,007, dated November 18, 2014 (Doc 209)	<input type="checkbox"/>
40	University of Western Australia v. Academisch Ziekenhuis Leiden, Azl List of Exhibits, as of November 18, 2014, 9 pages, Patent Interference No. 106,008, dated November 18, 2014 (Doc 212)	<input type="checkbox"/>
41	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL List of Proposed Motions, Patent Interference No. 106,007, 6 pages, dated September 10, 2014 (Doc 16)	<input type="checkbox"/>
42	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL List of Proposed Motions, Patent Interference No. 106,008, 8 pages, dated September 10, 2014 (Doc 15)	<input type="checkbox"/>
43	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Motion 1 (For Judgment that UWA's Claims are Unpatentable Under 35 U.S.C. sections 102 and 103), 69 pages, Patent Interference No. 106,007, dated November 18, 2014 (Doc 181)	<input type="checkbox"/>
44	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Motion 1 (For Judgment that UWA's Claims are Unpatentable Under 35 U.S.C. sections 102 and 103), 69 pages, Patent Interference No. 106,008, dated November 18, 2014 (Doc 184)	<input type="checkbox"/>

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Examiner Name	D. H. Shin
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45	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Motion 2 (To Deny UWA the Benefit of AU 2004903474), 23 pages, Patent Interference No. 106,007, dated November 18, 2014 (Doc 26)	<input type="checkbox"/>
46	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Motion 2 (To Deny UWA the Benefit of AU 2004903474), 24 pages, Patent Interference No. 106,008, dated November 18, 2014 (Doc 29)	<input type="checkbox"/>
47	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Motion 3 (For Judgment of Unpatentability based on Myriad) 20 pages, Patent Interference No. 106,008, dated November 18, 2014 (Doc 30)	<input type="checkbox"/>
48	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Motion 3 (For Judgment of Unpatentability based on Myriad), 19 pages, Patent Interference No. 106,007, dated November 18, 2014 (Doc 27)	<input type="checkbox"/>
49	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Notice of Related Proceedings, Patent Interference No. 106,007, 3 pages, dated July 31, 2014 (Doc 6)	<input type="checkbox"/>
50	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Notice of Related Proceedings, Patent Interference No. 106,008, 3 pages, dated August 5, 2014 (Doc 7)	<input type="checkbox"/>

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	Filing Date		2014-03-14	
	First Named Inventor	Richard K. BESTWICK		
	Art Unit	1674		
	Examiner Name	D. H. Shin		
	Attorney Docket Number	AVN-017		

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STATEMENT BY APPLICANT**
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Application Number # 30228	14213641
Filing Date	2014-03-14
First Named Inventor	Richard K. BESTWICK
Art Unit	1674
Examiner Name	D. H. Shin
Attorney Docket Number	AVN-017

1	SIERAKOWSKA, Halina et al., "Repair of thalassemic human beta-globin mRNA in mammalian cells by antisense oligonucleotides," Proc. Natl. Acad. Sci. USA, Vol. 93:12840-12844 (1996)	<input type="checkbox"/>
2	Sontheimer et al., "Metal ion catalysis during group II intron self-splicing: parallels with the spliceosome," Genes & Development, Vol. 13, pp. 1729-1741 (1999), Exhibit Number 1195 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
3	Sontheimer et al., "Three Novel Functional Variants of Human U5 Small Nuclear RNA," Vol. 12, No. 2, pp. 734-746 (Feb., 1992), Exhibit Number 1194 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
4	SONTHEIMER, Erik J. et al., "Metal ion catalysis during splicing of premessenger RNA," Nature, Vol. 388:801-805 (1997) (Exhibit Number 1036 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
5	SONTHEIMER, Erik J. et al., "The U5 and U6 Small Nuclear RNAs as Active Site Components of the Spliceosome," Science, Vol. 262:1989-1997 (1993) (Exhibit Number 1058 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
6	Standard Operating Procedure FPLC Desalting, Pages 6, Exhibit Number 1144 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
7	Stanton, Robert et al., "Chemical Modification Study of Antisense Gapmers", Nucleic Acid Therapeutics, Vol. 22(5): 344-359 (2012)	<input type="checkbox"/>
8	Statement On A Nonproprietary Name Adopted By the USAN Council, ETEPLIRSEN, Chemical Structure, 2010, pages 1-5.	<input type="checkbox"/>
9	STEIN, CA, "Delivery of antisense oligonucleotides to cells: a consideration of some of the barriers," Monographic supplement series: Oligos & Peptides - Chimica Oggi - Chemistry Today, Vol. 32(2):4-7 (2014) (Exhibit Number 2022 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
10	STEIN, Cy A. et al., "Therapeutic Oligonucleotides: The Road Not Taken," Clin. Cancer Res., Vol. 17(20):6369-6372 (2011) (Exhibit Number 2026 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
11	STEIN, David et al., "A Specificity Comparison of Four Antisense Types: Morpholino, 2'-O-Methyl RNA, DNA, and PHosphorothioate DNA," Antisense & Nucleic Acid Drug Development, Vol. 7:151-157 (1997)	<input type="checkbox"/>

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12	Strober JB, "Therapeutics in Duchenne muscular dystrophy," NeuroRX 2006; 3:225-34.	<input type="checkbox"/>
13	Summary of Professional Experience (Dr. Erik J. Sontheimer), Pages 4, Exhibit Number 1223 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
14	SUMMERTON, James et al., "Morpholino and Phosphorothioate Antisense Oligomers Compared in Cell-Free and In-Cell Systems," Antisense & Nucleic Acid Drug Development, Vol. 7:63-70 (1997)	<input type="checkbox"/>
15	SUMMERTON, James et al., "Morpholino Antisense Oligomers: Design, Preparation, and Properties," Antisense & Nucleic Acid Drug Development, Vol. 7:187-195 (1997)	<input type="checkbox"/>
16	SUMMERTON, James, "Morpholino antisense oligomers: the case for an RNase H-independent structural type," Biochimica et Biophysica Acta, Vol. 1489:141-158 (1999) (Exhibit Number 1038 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
17	Supplementary European Search Report for Application No. 10829367.1, 8 pages, dated May 22, 2013	<input type="checkbox"/>
18	Suter et al., "Double-target antisense U7 snRNAs promote efficient skipping of an aberrant exon in three human Beta-thalassemic mutations," 8:13 HUMAN MOLECULAR GENETICS 2415-2423 (1999) (Exhibit Number 1083 filed in interferences 106008, 106007 on December 23, 2014)	<input type="checkbox"/>
19	T HOEN, Peter A.C. et al., "Generation and Characterization of Transgenic Mice with the Full-length Human DMD Gene," The Journal of Biological Chemistry, Vol. 283(9):5899-5907 (2008) Exhibit Number 2030 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
20	Table 1: Primer and Product Details for Exon 51 and 53 Reports on AONs of 20 to 50 Nucleotides dd 07 JAN 2015, Pages 1, Exhibit Number 1177 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
21	Takeshima et al., "Oligonucleotides against a splicing enhancer sequence led to dystrophin production in muscle cells from a Duchenne muscular dystrophy patient," Brain & Dev., Vol. 23, pp. 788-790 (2001), Exhibit Number 1196 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
22	TAKESHIMA, Yasuhiro et al., "Modulation of In Vitro Splicing of the Upstream Intron by Modifying an Intra-Exon Sequence Which Is Deleted from the Dystrophin Gene in Dystrophin Kobe," J. Clin. Invest., Vol. 95:515-520 (1995)	<input type="checkbox"/>

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23	TANAKA, Kenji et al., "Polypurine Sequences within a Downstream Exon Function as a Splicing Enhancer," Molecular and Cellular Biology, Vol. 14(2):1347-1354 (1994)	<input type="checkbox"/>
24	THANH, Le Thiet et al., "Characterization of Revertant Muscle Fibers in Duchenne Muscular Dystrophy, Using Exon-Specific Monoclonal Antibodies against Dystrophin," Am. J. Hum. Genet., Vol. 56:725-731 (1995)	<input type="checkbox"/>
25	The Regents of the University of California v. Dako North America, Inc., U.S.D.C., N.D. California, No. C05-03955 MHP, April 22, 2009 (2009 WL 1083446 (N.D.Cal.), Exhibit Number 1206 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
26	TIAN, Xiaobing et al., "Imaging Oncogene Expression," Ann. N.Y. Acad. Sci., Vol. 1002:165-188 (2003) (Exhibit Number 2029 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
27	Transcript of 2nd Deposition of Erik J. Sontheimer, Ph.D., dated March 12, 2015, (Academisch Ziekenhuis Leiden Exhibit 1231, filed April 3, 2015 in Interference 106007 and 106008, pages 1-185).	<input type="checkbox"/>
28	Transcript of 2nd Deposition of Matthew J.A. Wood, M.D., D. Phil, dated March 5, 2015, (Academisch Ziekenhuis Leiden Exhibit 1230, filed April 3, 2015 in Interference 106007 and 106008, pages 1-117).	<input type="checkbox"/>
29	Transcript of December 12, 2014 Teleconference with Administrative Patent Judge Schafer (rough draft) (previously filed in Int. No. 106,008 as Ex. 2114), Pages 28 Exhibit Number 1001 filed in Interference 106,013 on February 17, 2015.	<input type="checkbox"/>
30	Transcript of the January 21, 2015 deposition of Erik Sontheimer, Ph.D., Patent Interference Nos. 106,007 and 106,008, 98 pages, dated January 21, 2015 (Exhibit Number 2122 filed in interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
31	Transcript of the March 11, 2015 deposition of Judith van Deutekom, Ph.D., (University of Western Australia Exhibit 2141, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-168).	<input type="checkbox"/>
32	Transcript of the March 12, 2015 deposition of Erik J. Sontheimer, Ph.D., (University of Western Australia Exhibit 2142, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-183).	<input type="checkbox"/>
33	Transcript of the March 5, 2015 deposition of Matthew J. A. Wood, M.D., D. PHIL., (University of Western Australia Exhibit 2146, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-115).	<input type="checkbox"/>

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Filing Date	2014-03-14
First Named Inventor	Richard K. BESTWICK
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Examiner Name	D. H. Shin
Attorney Docket Number	AVN-017

34	Transfection of AON, Pages 1, Exhibit Number 1170 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
35	U.S. Food and Drug Administration Statement, dated December 30, 2014 (2 pages), Exhibit Number 1204 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
36	U.S. Patent Application No. 12/198,007, as-filed August 25, 2008 ("the '007 Application") (Exhibit Number 1073 filed in interferences 106008, 106007 on December 23, 2014)	<input type="checkbox"/>
37	U.S. Patent Application No. 12/976,381, as-filed December 22, 2010 ("the '381 Application") (Exhibit Number 1074 filed in interferences 106008, 106007 on December 23, 2014)	<input type="checkbox"/>
38	U.S. Patent Application Publication No. 2001/0056077 ("Matsuo") 10 pages, (Exhibit Number 1080 filed in interferences 106008, 106007 on December 23, 2014)	<input type="checkbox"/>
39	U.S. Patent Application Publication No. 2002/0049173 ("Bennett et al.") 50 pages, (Exhibit Number 1081 filed in interferences 106008, 106007 on December 23, 2014)	<input type="checkbox"/>
40	U.S. Patent No. 5,190,931 ("the '931 Patent") 22 pages,(Exhibit Number 1069 filed in interferences 106008, 106007 on December 23, 2014)	<input type="checkbox"/>
41	U.S. Patent No. 7,001,761 (the "Xiao" Patent) 64 pages, (Exhibit Number 1070 filed in interferences 106008, 106007 on December 23, 2014)	<input type="checkbox"/>
42	University of Western Australia Objections to Opposition Evidence, served on February 24, 2015 filed in Interference No. 106,007, Exhibit 2150, filed April 10, 2015 in Interference Nos. 106007 and 106008, pages 1-15.	<input type="checkbox"/>
43	University of Western Australia Objections to Opposition Evidence, served on February 24, 2015, filed in Interference No. 106,008, Exhibit 2151, filed April 10, 2015, in Interference Nos. 106007 and 106008, pages 1-15.	<input type="checkbox"/>
44	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden List of Exhibits (as of Apr. 3, 2015), filed in Patent Interference No. 106,007, April 3, 2015, pages 1-18, (Doc 423).	<input type="checkbox"/>

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
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Application Number # 36232	14213641
Filing Date	2014-03-14
First Named Inventor	Richard K. BESTWICK
Art Unit	1674
Examiner Name	D. H. Shin
Attorney Docket Number	AVN-017

45	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden List of Exhibits (as of Apr. 3, 2015), filed in Patent Interference No. 106,008, April 3, 2015, pages 1-18 (Doc 435).	<input type="checkbox"/>
46	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden List of Exhibits, 18 pages, Patent Interference No. 106,007, (Doc 391), dated February 17, 2015.	<input type="checkbox"/>
47	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden List of Exhibits, 18 pages, Patent Interference No. 106,008, (Doc 398), dated February 17, 2015.	<input type="checkbox"/>
48	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden List of Exhibits, 3 pages, Patent Interference No. 106,013, (Doc 147), dated February 17, 2015.	<input type="checkbox"/>
49	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Notice of Service of Supplemental Evidence, 3 pages, Patent Interference No. 106,007 (Doc 414), dated March 9, 2015.	<input type="checkbox"/>
50	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Notice of Service of Supplemental Evidence, 3 pages, Patent Interference No. 106,008 (Doc 422), dated March 9, 2015.	<input type="checkbox"/>

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	Art Unit	1674	
	Examiner Name	D. H. Shin	
	Attorney Docket Number	AVN-017	

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Application Number # 36234		14213641
Filing Date		2014-03-14
First Named Inventor	Richard K. BESTWICK	
Art Unit	1674	
Examiner Name	D. H. Shin	
Attorney Docket Number	AVN-017	

1	US 8,592,386 (Mourich et al.), Pages 46, Exhibit Number 1095 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
2	US 8,618,270 (Iversen et al.), Pages 28, Exhibit Number 1096 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
3	US 8,637,483 (Wilton et al.), Pages 157, Exhibit Number 1097 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
4	US 8,697,858 (Iversen), Pages 95, Exhibit Number 1098 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
5	US 8,703,735 (Iversen et al.) Pages 73, Exhibit Number 1099 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
6	US 8,741,863 (Moulton et al.), Pages 68, Exhibit Number 1100 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
7	US 8,759,307 (Stein et al.), Pages 35, Exhibit Number 1101 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
8	US 8,779,128 (Hanson et al.), Pages 104, Exhibit Number 1102 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
9	US 8,785,407 (Stein et al.), Pages 35, Exhibit Number 1103 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
10	US 8,785,410 (Iversen et al.), Pages 20, Exhibit Number 1104 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
11	US 8,835,402 (Kole et al.), Pages 27, Exhibit Number 1105 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>

**INFORMATION DISCLOSURE
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Application Number	14213641
Filing Date	2014-03-14
First Named Inventor	Richard K. BESTWICK
Art Unit	1674
Examiner Name	D. H. Shin
Attorney Docket Number	AVN-017

12	US 8,865,883 (Sazani et al.), Pages 199, Exhibit Number 1106 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
13	US 8,871,918 (Sazani et al.), Pages 195, Exhibit Number 1107 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
14	US 8,877,725 (Iversen et al.), Pages 34, Exhibit Number 1108 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
15	US 8,895,722 (Iversen et al.), Pages 29, Exhibit Number 1109 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
16	US 8,906,872 (Iversen et al.), Pages 69, Exhibit Number 1110 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
17	US Abandonment for Application No. 13/902,376, 1 page, dated June 12, 2014 (Exhibit Number 1047 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
18	US Amendment After Non-Final Action for Application No. 11/233,495, 31 pages, dated June 24, 2010 (Exhibit Number 2073 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
19	US Amendment for Application No. 11/233,495, 15 pages, dated April 1, 2009 (Exhibit Number 2071 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
20	US Amendment for Application No. 11/233,495, 19 pages, dated September 16, 2009 (Exhibit Number 2072 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
21	US Amendment for Application No. 11/233,495, 9 pages, dated October 31, 2007 (Exhibit Number 2070 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
22	US Amendment for Application No. 11/570,691, 9 pages, dated June 15, 2010 (Exhibit Number 1043 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>

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23	US Amendment for Application No. 13/271,080, 30 pages, dated January 30, 2013 (Exhibit Number 1049 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
24	US Amendment for Application No. 13/902,376, 36 pages, dated March 21, 2014 (Exhibit Number 1046 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
25	US Amendment in Response to Advisory Action for Application No. 11/233,495, 23 pages, dated March 14, 2011 (Exhibit Number 2074 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
26	US Amendments to the Claims for Application No. 11/233,495, 4 pages, dated May 8, 2014 (Exhibit Number 2077 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
27	US Amendments to the Claims for Application No. 14/198,992, 3 pages, dated July 16, 2014 (Exhibit Number 2079 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
28	US Applicant-Initiated Interview Summary and Notice of Allowance for Application No. 13/550,210, 9 pages dated May 19, 2014 (Exhibit Number 2076 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
29	US application as-filed and Preliminary Amendment for Application No. 13/550,210, 59 pages dated July 16, 2012 (Exhibit Number 2087 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
30	US Application as-filed for application No. 14/198,992, 52 pages, dated March 6, 2014 (Exhibit Number 2086 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
31	US Application as-filed, Application Data Sheet, and Preliminary Amendment for Application No. 12/837,359, 101 pages, dated July 15, 2010 (Exhibit Number 2100 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
32	US Application for Letters Patent for Application No. 11/233,495 as-filed and preliminary amendment, 77 pages, dated September 21, 2005 (Exhibit Number 2095 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
33	US Application No. 11/233,495, 74 pages; excerpts of prosecution history including: US Supplemental Amendment and Response dated May 8, 2014; Second Supplemental Response dated July 25, 2013; Supplemental Amendment dated June 26, 2013; Amendment after Non-final Action dated November 1, 2010; Amendment under 35 USC 1.114 dated September 16, 2009 (Exhibit Number 2054 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>

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Attorney Docket Number	AVN-017

34	US Application No. 14/198,992, 17 pages; excerpts of prosecution history including: Supplemental Amendment dated July 16, 2014; Response to Non-Final Office Action dated July 14, 2014 (Exhibit Number 2056 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
35	US Application No. 14/248,279, 29 pages; excerpts of prosecution history including: Amendment under 37 CFR 1.312 dated September 19, 2014; Amendment in Response to Final Office Action dated August 7, 2014; Declaration under 37 CFR 1.132 dated May 26, 2014; Declaration under 37 CFR 1.132 dated May 27, 2014; Response dated June 3, 2014 (Exhibit Number 2057 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
36	US Application No.13/550,210, 27 pages; excerpts of prosecution history including: Response and Amendment dated May 12, 2014; Response to Non-Final Office Action dated January 21, 2014; Second Preliminary Amendment dated January 3, 2013 (Exhibit Number 2055 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
37	US claim amendments for Application No. 13/550,210, 3 pages, dated May 12, 2014 (Exhibit Number 2078 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
38	US Claims for Application No. 12/976,381, 1 page, dated December 22, 2010 (Exhibit Number 2065 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
39	US Declaration of Richard K. Bestwick, for Application No. 11/570,691, 5 pages, dated June 15, 2010 (Exhibit Number 1044 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
40	US E-mail from Patent Trial and Appeal Board to Danny Huntington, 2 pages, dated October 9, 2014 (Exhibit Number 2002 filed in interferences 106008 on October 17, 2014)	<input type="checkbox"/>
41	US Non-Final Office Action for Application No. 11/570,691, 16 pages, dated March 15, 2010 (Exhibit Number 1042 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
42	US Office Action for Application No. 13/271,080, 25 pages, dated July 30, 2012 (Exhibit Number 1048 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
43	US Office Action for Application No. 13/550,210, 12 pages, dated September 27, 2013 (Exhibit Number 2080 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
44	US Office Action for Application No. 13/902,376, 7 pages, dated January 7, 2014 (Exhibit Number 1045 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>

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Application Number # 36238	14213641
Filing Date	2014-03-14
First Named Inventor	Richard K. BESTWICK
Art Unit	1674
Examiner Name	D. H. Shin
Attorney Docket Number	AVN-017

45	US Patent Application No. 12/198,007 as-filed, 64 pages, dated August 25, 2008 (Exhibit Number 2092 filed in interferences 106008, 106013, and 106007 on November 18, 2014)	<input type="checkbox"/>
46	US Preliminary Amendment and application as-filed for Application No. 12/976,381, 64 pages, dated December 22, 2010 (Exhibit No. 2089 filed in Interferences 106007, 106008, and 106013 on November 18, 2014)	<input type="checkbox"/>
47	US Preliminary Amendment for Application No. 11/233,495, 10 pages, dated September 21, 2005 (Exhibit Number 2069 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
48	US Preliminary Remarks for Application No. 14/198,992, 1 page, dated March 6, 2014 (Exhibit Number 2097 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
49	US Proposed Terminal Disclaimer for Application No. 12/860,078, 2 pages, dated October 17, 2014 (Exhibit Number 2001 filed in interference 106008 on October 17, 2014)	<input type="checkbox"/>
50	US Remarks for Application No. 14/248,279, 2 pages, dated August 27, 2014 (Exhibit Number 2110 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>

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	Art Unit	1674		
	Examiner Name	D. H. Shin		
	Attorney Docket Number	AVN-017		

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1	HERSCHLAG, Daniel et al., "Contributions of 2' Hydroxyl Groups of the RNA Substrate to Binding and Catalysis by the Tetrahymena Ribozyme: An Energetic Picture of an Active Site Composed of RNA," Biochemistry, Vol. 32:8299-8311 (1993) (Exhibit Number 1031 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
2	Hoffman EP, et al., "Characterization of dystrophin in muscle-biopsy specimens from patients with Duchenne's or Becker's muscular dystrophy" N Engl J Med 1988;318:1363-68.	<input type="checkbox"/>
3	Hoffman EP, et al., "Restoring dystrophin expression in Duchenne muscular dystrophy muscle: Progress in exon skipping and stop codon read through," Am J Path 2011;179:12-22.	<input type="checkbox"/>
4	HUDZIAK, Robert M. et al., "Antiproliferative Effects of Steric Blocking Phosphorodiamidate Morpholino Antisense Agents Directed against c-myc," Antisense & Nucleic Acid Drug Development, Vol. 10:163-176 (2000) (Exhibit Number 1032 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
5	HUDZIAK, Robert M. et al., "Resistance of Morpholino Phosphorodiamidate Oligomers to Enzymatic Degradation," Antisense & Nucleic Acid Drug Development, Vol. 6:267-272 (1996)	<input type="checkbox"/>
6	HUSSEY, Nicole D. et al., "Analysis of five Duchenne muscular dystrophy exons and gender determination using conventional duplex polymerase chain reaction on single cells," Molecular Human Reproduction, Vol. 5(11):1089-1094 (1999)	<input type="checkbox"/>
7	Interim Guidance on Patent Subject Matter Eligibility ("the December Guidance," 16 pages,(Exhibit Number 2119 filed in interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
8	International Patent Application No. PCT/AU2000/00693 ("Wright"), published as WO 00/78341 on December 28, 2000, 201 pages, (Exhibit Number 2125 filed in interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
9	International Preliminary Report on Patentability and Written Opinion for Application No. PCT/US2009/061960, 8 pages, dated April 26, 2011	<input type="checkbox"/>
10	International Preliminary Report on Patentability for Application No. PCT/AU2005/000943, 8 pages, dated December 28, 2006	<input type="checkbox"/>
11	International Preliminary Report on Patentability, PCT/US2013/077216, dated June 23, 2015, pages 1-7.	<input type="checkbox"/>

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12	International Preliminary Report on Patentability, PCT/US2014/029610, dated July 1, 2015, pages 1-122.	<input type="checkbox"/>
13	International Preliminary Report on Patentability, PCT/US2014/029766, dated September 15, 2015, pages 1-10.	<input type="checkbox"/>
14	International Search Report and Written Opinion of the International Searching Authority issued in International Patent Application No. PCT/US2013/077216, 5 pages, dated March 27, 2014	<input type="checkbox"/>
15	International Search Report and Written Opinion of the International Searching Authority issued in International Patent Application No. PCT/US2014/029610, 6 pages, dated September 18, 2014	<input type="checkbox"/>
16	International Search Report and Written Opinion of the International Searching Authority issued in International Patent Application No. PCT/US2014/029689, 8 pages, dated October 21, 2014	<input type="checkbox"/>
17	International Search Report and Written Opinion of the International Searching Authority issued in International Patent Application No. PCT/US2014/029766, 8 pages, dated October 21, 2014	<input type="checkbox"/>
18	International Search Report for Application No. PCT/AU2005/000943, 5 pages, dated October 20, 2005	<input type="checkbox"/>
19	International Search Report for Application No. PCT/US01/14410, 5 pages, dated March 6, 2002	<input type="checkbox"/>
20	International Search Report for Application No. PCT/US2009/061960, 9 pages, dated April 6, 2010	<input type="checkbox"/>
21	Invitation to pay fees and Partial International Search Report issued by the International Search Authority in International Patent Application No. PCT/US2014/029689, 8 pages, dated July 29, 2014	<input type="checkbox"/>
22	ISIS Pharmaceuticals website, 2 pages, http://www.isispharm.com/Pipeline/Therapeutic-Areas/Other.htm (2014) (Exhibit Number 2021 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>

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23	IVERSEN, Patrick L. et al., "Efficacy of Antisense Morpholino Oligomer Targeted to c-myc in Prostate Cancer Xenograft Murine Model and a Phase I Safety Study in Humans," Clinical Cancer Research, Vol. 9:2510-2519 (2003)	<input type="checkbox"/>
24	JARVER, Peter et al., "A Chemical View of Oligonucleotides for Exon Skipping and Related Drug Applications," Nucleic Acid Therapeutics, Vol. 24(1):37-47 (2014) (Exhibit Number 2061 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
25	JASON, Tracey L.H. et al., "Toxicology of antisense therapeutics," Toxicology and Applied Pharmacology, Vol. 201:66-83 (2004) (Exhibit Number 2027 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
26	JEARAWIRIYAPAISARN, Natee et al., "Long-term improvement in mdx cardiomyopathy after therapy with peptide-conjugated morpholino oligomers," Cardiovascular Research, Vol. 85:444-453 (2010)	<input type="checkbox"/>
27	JEARAWIRIYAPAISARN, Natee et al., "Sustained Dystrophin Expression Induced by Peptide-conjugated Morpholino Oligomers in the Muscles of mdx Mice," Mol. Ther., Vol. 16(9):1624-1629 (2008)	<input type="checkbox"/>
28	Job Posting by Sarepta for "Scientist II, Muscle Biology" (2 pages), (Academisch Ziekenhuis Leiden Exhibit 1233, filed April 3, 2015 in Interference 106007 and 106008).	<input type="checkbox"/>
29	JONES, Simon S. et al., "The Protection of Uracil and Guanine Residues in Oligonucleotide Synthesis," Tetrahedron Letters, Vol. 22(47):4755-4758 (1981)	<input type="checkbox"/>
30	KARLEN, Yann et al., "Statistical significance of quantitative PCR," BMC Bioinformatics, 8:131, 16 pages (2007) (Exhibit Number 1033 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
31	KARRAS, James G. et al., "Deletion of Individual Exons and Induction of Soluble Murine Interleukin-5 Receptor-alpha Chain Expression through Antisense Oligonucleotide-Mediated Redirection of Pre-mRNA splicing," Molecular Pharmacology, Vol. 58:380-387 (2000)	<input type="checkbox"/>
32	KAYE, Ed, "Results of the Eteplirsen Phase 2b and Phase 2b Extension Study in Duchenne Muscular Dystrophy," 8th Annual Meeting of the Oligonucleotide Therapeutics Society, Session 9: Advances in Oligonucleotide Clinical Development II, Page 48 (2012)	<input type="checkbox"/>
33	KINALI, Maria et al., "Local restoration of dystrophin expression with the morpholino oligomer AVI-4658 in Duchenne muscular dystrophy: a single-blind, placebo-controlled, dose-escalation, proof-of-concept study," Lancet Neurol., Vol. 8:918-928 (2009)	<input type="checkbox"/>

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34	King et al., "A Dictionary of Genetics," Oxford University Press, 4th Ed. (1990), Exhibit Number 1189 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
35	KOENIG, M. et al., "The Complete Sequence of Dystrophin Predicts a Rod-Shaped Cytoskeleton Protein," Cell, Vol. 53:219-228 (1988) (Exhibit Number 1010 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
36	KOENIG, M. et al., "The Molecular Basis for Duchenne versus Becker Muscular Dystrophy: Correlation of Severity with Type of Deletion," Am. J. Hum. Genet., Vol. 45:498-506 (1989) (Exhibit Number 1011 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
37	Kohler M, et al., "Quality of life, physical disability and respiratory impairment in Duchenne muscular dystrophy," Am J Respir Crit Care Med 2005;172:1032-6.	<input type="checkbox"/>
38	KOSHKIN, Alexei A. et al., "LNA (Locked Nucleic Acids): Synthesis of the Adenine, Cytosine, Guanine, 5-Methylcytosine, Thymine and Uracil Bicyclonucleoside Monomers, Oligomerisation, and Unprecedented Nucleic Acid Recognition," Tetrahedron, Vol. 54:3607-3630 (1998) (Exhibit Number 2007 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
39	Kurreck J., "Antisense Technologies: Improvement Through Novel Chemical Modifications", European Journal of Biochemistry, Vol.270(8):1628-1644 (2003)	<input type="checkbox"/>
40	Lab-on-a-Chip Data, Pages 28, Exhibit Number 1185 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
41	Laboratory Notebook Entry (Exon 51 Experiments): RT-PCR Analysis of 8036 Cells, Pages 2, Exhibit Number 1179 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
42	Laboratory Notebook Entry (Exon 51 Experiments): RT-PCR Analysis of KM155.C25 Cells, Pages 2, Exhibit Number 1178 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
43	Laboratory Notebook Entry (Exon 51 Experiments): Transfection of 8036 Cells, Pages 1, Exhibit Number 1172 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
44	Laboratory Notebook Entry (Exon 51 Experiments): Transfection of KM155.C25 Cells, Pages 1, Exhibit Number 1171 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>

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Art Unit	1674	
Examiner Name	D. H. Shin	
Attorney Docket Number	AVN-017	

45	Laboratory Notebook Entry (Exon 53 Experiments): RT-PCR Analysis of KM155.C25 Cells, Pages 2, Exhibit Number 1180 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
46	Laboratory Notebook Entry (Exon 53 Experiments): RT-PCR Analysis of R1809 Cells, Pages 2, Exhibit Number 1181 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
47	Laboratory Notebook Entry (Exon 53 Experiments): Transfection of KM155.C25 Cells, Pages 1, Exhibit Number 1173 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
48	Laboratory Notebook Entry (Exon 53 Experiments): Transfection of R1809 Cells, Pages 1, Exhibit Number 1174 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
49	Laboratory Notebook Entry: General RNA recovery, 1 Page, Exhibit Number 1176 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
50	Laboratory Notebook Entry: Lab-on-a-Chip Analysis, Pages 3, Exhibit Number 1184 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>

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Application No.: 14/213,641 (Information Disclosure Statement)

Docket No.: AVN-017

Applicants call to the attention of the Examiner the following Office Actions from
Applications previously made of record:

/Dana Shin/

10/13/2015

Office Actions (copies enclosed)			
Examiner's Initials	Serial No.	Date Mailed from USPTO	Examiner
	14/223,634	April 15, 2015	Kimberly Chong
	14/317,952	March 18, 2015	Kimberly Chong
	14/213,607	September 15, 2015	D.H. Shin
	14/213,607	April 1, 2015	D.H. Shin
	14/214,480	April 17, 2015	D.H. Shin
	14/108,137	April 29, 2015	T.A. Vivlemore
	14/213,629	August 21, 2015	E. Poliakova-Georgan
	13/826,880	June 22, 2015	Kimberly Chong
	14/214,567	June 24, 2015	E. Poliakova-Georgan

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	Examiner Name	D. H. Shin		
	Attorney Docket Number	AVN-017		

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STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	14213641
Filing Date	2014-03-14
First Named Inventor	Richard K. BESTWICK
Art Unit	1674
Examiner Name	D. H. Shin
Attorney Docket Number	AVN-017

1	Partial European Search Report for Application No. 12162995.0, 6 pages, dated October 2, 2012	<input type="checkbox"/>
2	Patentee's Response to European Patent Application No. 05076770.6, dated July 28, 2006, 4 pages	<input type="checkbox"/>
3	Patrick O. Brown and Tidear D. Shalon v. Stephen P.A. Fodor, Dennis W. Solas and William J. Dower: Interference Merits Panel, Interference No. 104,358, 24 pages, dated August 9, 1999 (Exhibit Number 2113 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
4	PCT Application as-filed for application No. PCT/NL03/00214, 71 pages, dated September 21, 2005 (Exhibit Number 2042 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
5	PD-10 Desalting Columns, Pages 12, Exhibit Number 1141 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
6	POPPELWELL, Linda et al., "Design of phosphorodiamidate morpholino oligmers (PMOs) for the induction of exon skipping of the human DMD gene," Human Gene Therapy 19(10): ESGCT 2008 Poster Presentations, Page 1174, Poster No. P203	<input type="checkbox"/>
7	POPPELWELL, Linda J. et al., "Comparative analysis of antisense oligonucleotide sequences targeting exon 53 of the human DMD gene: Implications for future clinical trials," Neuromuscular Disorders, Vol. 20(2):102-110 (2010) 9 pages (Exhibit Number 2031 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
8	POPPELWELL, Linda J. et al., "Design of Antisense Oligonucleotides for Exon Skipping of the Human Dystrophin Gene," Human Gene Therapy 19(4): BSGT 2008 Poster Presentation, Page 407, Poster No. P-35	<input type="checkbox"/>
9	POPPELWELL, Linda J. et al., "Design of Phosphorodiamidate Morpholino Oligomers (PMOs) for the Induction of Exon Skipping of the Human DMD Gene," Molecular Therapy, Vol. 17(3):554-561 (2009)	<input type="checkbox"/>
10	POPPELWELL, Linda J. et al., "Targeted Skipping of Exon 53 of the Human DMD Gene Recommendation of the Highly Efficient Antisense Oligonucleotide for Clinical Trial," Human Gene Therapy 20(4): BSGT 2009 Poster Presentations, Page 399, Poster No. P10	<input type="checkbox"/>
11	Poster Abstract Listing for The Tenth Annual Meeting of the RNA Society, held at the Banff Centre for Conferences, in Banff, Alberta, Canada, from May 24-29, 2005, (University of Western Australia Exhibit 2137, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-11).	<input type="checkbox"/>

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12	Pramono, "Induction of Exon Skipping of the Dystrophin Transcript in Lymphoblastoid Cells by Transfecting an Antisense Oligodeoxynucleotide Complementary to an Exon Recognition Sequence," Biochem. and Biophys. Res. Comm., Vol. 226, pp. 445-449 (1996), Exhibit Number 1192 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
13	Preliminary Amendment for Application No. 12/976,381, 4 pages, dated December 22, 2010 (Exhibit Number 2066 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
14	Preliminary Amendment for Application No. 12/198,007, 3 pages, dated November 7, 2008 (Exhibit Number 2067 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
15	Program Schedule for The Tenth Annual Meeting of the RNA Society, held at the Banff Centre for Conferences, in Banff, Alberta, Canada, from May 24-29, 2005, (University of Western Australia Exhibit 2136, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-4).	<input type="checkbox"/>
16	Proliferation and Differentiation of Myoblast Cultures, Pages 2, Exhibit Number 1169 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
17	Prosensa Press Release, dated October 10, 2014 (2 pages), Exhibit Number 1203 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
18	Prosensa, "GSK and Prosensa Announce Primary Endpoint Not Met in Phase III Study of Drisapersen in Patients With Duchenne Muscular Dystrophy," press release, 4 pages, dated September 20, 2013 (Exhibit Number 2039 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
19	Raz et al. v. Davis et al., Board of Patent Appeals and Interferences, Patent and Trademark Office, Int. No. 105,712, Tech. Ctr. 1600, September 29, 2011 (24 pages) (2011 WL 4568986 (Bd.Pat.App. & Interf.)), Exhibit Number 1209 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
20	REESE, Colin B. et al., "Reaction Between 1-Arenesulphonyl-3-Nitro-1,2,4-Triazoles and Nucleoside Base Residues. Elucidation of the Nature of Side-Reactions During Oligonucleotide Synthesis," Tetrahedron Letters, Vol. 21:2265-2268 (1980)	<input type="checkbox"/>
21	REESE, Colin B. et al., "The Protection of Thymine and Guanine Residues in Oligodeoxyribonucleotide Synthesis," J. Chem. Soc. Perkin Trans. 1, pages 1263-1271 (1984)	<input type="checkbox"/>
22	Reexamination Certificate - Application No. 90/011,320, issued March 27, 2012, 2 pages, (Exhibit Number 1072 filed in interferences 106008, 106007 on December 23, 2014)	<input type="checkbox"/>

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36249

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23	Reply to EPO Communication dated June 26, 2014 in European Application Serial No. 13160338, (University of Western Australia Exhibit 2145, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-4).	<input type="checkbox"/>
24	Reply to EPO Communication dated October 21, 2014 in European Application Serial No. 12198517, (University of Western Australia Exhibit 2148, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-7).	<input type="checkbox"/>
25	Reply to EPO Communication dated October 23, 2014 in European Application Serial No. 12198485, (University of Western Australia Exhibit 2147, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-8).	<input type="checkbox"/>
26	Response to Office Action and Amendments to the Claims for Application No. 13/550,210, 10 pages, dated May 12, 2014 (Exhibit Number 2064 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
27	Rhodes et al., "BioMarin Bulks Up," BioCentury, pp. 6-8 (December, 2014), Exhibit Number 1193 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
28	RNA Isolation Using RNA-BEE, Pages 1, Exhibit Number 1175 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
29	ROBERTS, Roland G. et al., "Exon Structure of the Human Dystrophin Gene," Genomics, Vol. 16:536-538 (1993)	<input type="checkbox"/>
30	Roest et al., "Application of In Vitro Myo-Differentiation of Non-Muscle Cells to Enhance Gene Expression and Facilitate Analysis of Muscle Proteins," Neuromuscul. Disord., Vol. 6, No. 3, pp. 195-202 (May, 1996), Exhibit Number 1124 filed in interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
31	ROSSO, Mario G. et al., "An Arabidopsis thaliana T-DNA mutagenized population (GABI-Kat) for flanking sequence tag-based reverse genetics," Plant Molecular Biology, Vol. 53:247-259 (2003)	<input type="checkbox"/>
32	Saito, T. et al., "First-in-Human Study of NS-065/NCNP-01; the Morpholino Based Antisense Oligonucleotide for Exon 53 Skipping in Duchenne Muscular Dystrophy," ASGCT meeting , May 13, 2015, Abstract [136] 1 page.	<input type="checkbox"/>
33	Saito, T. et al., "First-in-Human Study of NS-065/NCNP-01; the Morpholino Based Antisense Oligonucleotide for Exon 53 Skipping in Duchenne Muscular Dystrophy," ASGCT meeting , May 13, 2015, pages 1-11.	<input type="checkbox"/>

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Attorney Docket Number	AVN-017

34	Sarepta Therapeutics Press Release, dated January 12, 2015, Exhibit Number 1119 filed in interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
35	Sarepta, "AVI BioPharma Initiates Dosing in Phase 2 Study of Eteplirsen in Duchenne Muscular Dystrophy Patients," press release, 4 pages, dated August 15, 2011 (Exhibit Number 2082 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
36	Sarepta, "Sarepta Therapeutics Announces Eteplirsen Demonstrates Continued Stability on Walking Test through 120 Weeks in Phase IIB Study in Duchenne Muscular Dystrophy," press release, 3 pages, dated January 15, 2014 (Exhibit Number 2034 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
37	Sarepta, "Sarepta Therapeutics Reports Long-Term Outcomes through 144 Weeks from Phase IIB Study of Eteplirsen in Duchenne Muscular Dystrophy," press release, http://investorrelations.sarepta.com/phoenix.zhtml?c=64231&p=irol-newsArticle&id=1946426 , 4 pages, dated July 10, 2014	<input type="checkbox"/>
38	Scully, Michele et al., "Review of Phase II and Phase III Clinical Trials for Duchenne Muscular Dystrophy", Expert Opinion on Orphan Drugs, Vol.1(1):33-46 (2013)	<input type="checkbox"/>
39	Second Preliminary Amendment filed in US Application No. 13/550,210, 5 pages, dated January 3, 2013 (Exhibit Number 2062 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
40	Second Written Opinion for Application No. PCT/AU2010/001520, 7 pages, dated October 13, 2011	<input type="checkbox"/>
41	Semi Quantitative Lab-on-Chip Analysis of Second PCR Product, Pages 1, Exhibit Number 1183 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
42	Sequence Listing - Serial No. 13/550,210, as filed July 16, 2012 (9 pages), Exhibit Number 1205 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
43	Sequence of Exon 46 of Dystrophin Gene, 1 page	<input type="checkbox"/>
44	Sequence of Exon 51 of Dystrophin Gene, 1 page	<input type="checkbox"/>

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45	Shabanpoor et al., "Bi-specific splice-switching PMO oligonucleotides conjugated via a single peptide active in a mouse model of Duchenne muscular dystrophy," Nucleic Acids Res., pp. 1-11 (December, 2014), Exhibit Number 1114 filed in interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
46	SHAPIRO, Marvin B. et al., "RNA splice junctions of different classes of eukaryotes: sequence statistics and functional implications in gene expression," Nucleic Acids Research, Vol. 15(17):7155-7174 (1987)	<input type="checkbox"/>
47	SHERRATT, Tim G. et al., "Exon Skipping and Translation in Patients with Frameshift Deletions in the Dystrophin Gene," Am. J. Hum. Genet., Vol. 53:1007-1015 (1993)	<input type="checkbox"/>
48	SHIGA, Nobuyuki et al., "Disruption of the Splicing Enhancer Sequence within Exon 27 of the Dystrophin Gene by a Nonsense Mutation Induced Partial Skipping of the Exon and Is Responsible for Becker Muscular Dystrophy," J. Clin. Invest., Vol. 100(9):2204-2210 (1997)	<input type="checkbox"/>
49	SHIMIZU, Miho et al., "Oligo(2'-O-methyl)ribonucleotides Effective probes for duplex DNA," FEBS Letters, Vol. 302 (2):155-158 (1992) (Exhibit Number 1035 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
50	Siemens Healthcare Diagnostics, Inc. v. Enzo Life Sciences, Inc., 2013 WL 4411227, *11 [Parallel cite: U.S.D.C., D. Mass., Civil No. 10-40124-FDS], Decided Aug. 14, 2013 (12 pages); [Cited as: 2013 WL 4411227], Exhibit Number 1210 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>

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	Filing Date		2014-03-14	
	First Named Inventor	Richard K. BESTWICK		
	Art Unit	1674		
	Examiner Name	D. H. Shin		
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Application Number
30253

14213641

**INFORMATION DISCLOSURE
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Filing Date	2014-03-14
First Named Inventor	Richard K. BESTWICK
Art Unit	1674
Examiner Name	D. H. Shin
Attorney Docket Number	AVN-017

1	US Response and amendments for Application No. 13/550,210, 12 pages, dated January 21, 2014 (Exhibit Number 2063 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
2	US Revised Figure 4H, US Application No. 13/271,080, 1 page (Exhibit Number 1050 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
3	US Terminal Disclaimer for Application No. 14/198,992, 1 page, dated July 15, 2014 (Exhibit Number 2096 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
4	US Terminal Disclaimer for Application No. 14/248,279, 1 page, dated August 7, 2014 (Exhibit Number 2109 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
5	US Track One Request, Application as-filed, and Application Data Sheet for Application No. 14/248,279, 68 pages, dated April 8, 2014 (Exhibit Number 2108 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
6	US Transmittal, application as-filed, and Preliminary Amendment for Application No. 11/570,691, 102 pages, dated December 15, 2006 (Exhibit Number 2103 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
7	US Transmittal, application as-filed, and Preliminary Amendment for Application No. 13/270,992, 101 pages, dated October 11, 2011 (Exhibit Number 2098 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
8	US Transmittal, application as-filed, and Preliminary Amendment for Application No. 13/271,080, 115 pages, dated October 11, 2011 (Exhibit Number 2111 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
9	US Updated Filing Receipt for Application No. 13/550,210, 3 pages, dated December 11, 2012 (Exhibit Number 2044 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
10	USPTO "2014 Procedure for Subject Matter Eligibility Analysis of Claims Reciting or Involving...Natural Products" ("the March Guidance"), 19 pages, (Exhibit Number 2118 filed in interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
11	USPTO Written Description Training Materials, Revised March 25, 2008, Example 12, 6 pages, (Exhibit Number 1068 filed in interferences 106008, 106007 on December 23, 2014)	<input type="checkbox"/>

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12	UWA Clean Copy of Claims and Sequence, as filed in Interference No. 106,007 on August 1, 2014 (Paper 12), 8 pages, (Exhibit Number 2126 filed in interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
13	UWA Clean Copy of Claims and Sequence, as filed in Interference No. 106,007 on August 7, 2014 (Paper 12), 8 pages, (Exhibit Number 2127 filed in interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
14	UWA Motion 1 (For Judgment Under 35 § 112(a)) from Int. No. 106,007 (PN210), 40 Pages, Exhibit Number 1005 filed in Interference 106,013 on February 17, 2015.	<input type="checkbox"/>
15	UWA Motion 1 (For Judgment Under 35 § 112(a)) from Int. No. 106,008 (Doc 213), Pages 38, Exhibit Number 1004 filed in Interference 106,013 on February 17, 2015.	<input type="checkbox"/>
16	UWA submission of teleconference transcript , 28 pages, dated December 12, 2014 (Exhibit Number 2114 filed in interferences 106008 and 106007 on December 12, 2014)	<input type="checkbox"/>
17	Valorization Memorandum published by the Dutch Federation of University Medical Centers in March 2009, (University of Western Australia Exhibit 2140, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-33).	<input type="checkbox"/>
18	VAN DEUTEKOM et al., "Antisense-induced exon skipping restores dystrophin expression in DMD patient derived muscle cells," HUMAN MOLECULAR GENETICS Vol. 10, No. 15: 1547-1554 (2001) (Exhibit Number 1084 filed in interferences 106008, 106007 on December 23, 2014)	<input type="checkbox"/>
19	van Deutekom et al., "Local Dystrophin Restoration with Antisense Oligonucleotide PRO051," N. Engl. J. Med., Vol. 357, No. 26, pp. 2677-2686 (December, 2007), Exhibit Number 1213 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
20	VAN DEUTEKOM, Judith C. T. et al., "Advances in Duchenne Muscular Dystrophy Gene Therapy," Nature Reviews Genetics, Vol. 4(10):774-783 (2003)	<input type="checkbox"/>
21	Van Ommen 2002 PCT (WO 02/24906 AI), 43 pages,(Exhibit Number 1071 filed in interferences 106008, 106007 on December 23, 2014)	<input type="checkbox"/>
22	van Putten M, et al., "The Effects of Low Levels of Dystrophin on Mouse Muscle Function and Pathology. PLoS ONE 2012;7:e31937, 13 pages	<input type="checkbox"/>

Application Number
30255

14213641

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2014-03-14

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Richard K. BESTWICK

Art Unit

1674

Examiner Name

D. H. Shin

Attorney Docket Number

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23	Van Vliet, Laura et al., "Assessment of the Feasibility of Exon 45-55 Multiexon Skipping for Duchenne Muscular Dystrophy", BMC Medical Genetics, Vol.9(1):105 (2008)	<input type="checkbox"/>
24	VERMA, Sandeep et al., "Modified Oligonucleotides: Synthesis and Strategy for Users," Annu. Rev. Biochem., Vol. 67:99-134 (1998) (Exhibit Number 1040 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
25	VOIT, Thomas et al., "Safety and efficacy of drisapersen for the treatment of Duchenne muscular dystrophy (DEMAND II): an exploratory, randomised, placebo-controlled phase 2 study," Lancet Neurol., Vol. 13:987-996 (2014) (Exhibit Number 2037 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
26	VOLLOCH, Vladimir et al., "Inhibition of Pre-mRNA Splicing by Antisense RNA in Vitro: Effect of RNA Containing Sequences Complementary to Exons," Biochemical and Biophysical Research Communications, Vol. 179 (3):1593-1599 (1991)	<input type="checkbox"/>
27	Wahlestedt et al., "Potent and nontoxic antisense oligonucleotides containing locked nucleic acids," PNAS, Vol. 97, No. 10, pp. 5633-5638 (May, 2000), Exhibit Number 1201 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
28	Wang et al., "In Vitro evaluation of novel antisense oligonucleotides is predictive of in vivo exon skipping activity for Duchenne muscular dystrophy," J. Gene Medicine, Vol. 12, pp. 354-364 (March, 2010), Exhibit Number 1115 filed in interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
29	WANG, Chen-Yen et al., "pH-sensitive immunoliposomes mediate target-cell-specific delivery and controlled expression of a foreign gene in mouse," Proc. Natl. Acad. Sci. USA, Vol. 84:7851-7855 (1987)	<input type="checkbox"/>
30	WATAKABE, Akiya et al., "The role of exon sequences in splice site selection," Genes & Development, Vol. 7:407-418 (1993)	<input type="checkbox"/>
31	Watanabe et al., "Plasma Protein Binding of an Antisense Oligonucleotide Targeting Human ICAM-1 (ISIS 2302)," Oligonucleotides, Vol. 16, pp. 169- 180 (2006), Exhibit Number 1197 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
32	WIJNAENDTS, L.C.D. et al., "Prognostic importance of DNA flow cytometric variables in rhabdomyosarcomas," J. Clin. Pathol., Vol. 46:948-952 (1993) (Exhibit Number 1041 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
33	Wilton et al. (2007) "Antisense Oligonucleotide-induced Exon Skipping Across the Human Dystrophin Gene Transcript," Molecular Therapy 15(7):1288-1296, 10 pages, (Exhibit Number 2121 filed in interferences 106,007 and 106,008 on February 17, 2015)	<input type="checkbox"/>

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34	WILTON, Stephen D. et al., "Antisense oligonucleotides in the treatment of Duchenne muscular dystrophy: where are we now?" Neuromuscular Disorders, Vol. 15:399-402 (2005)	<input type="checkbox"/>
35	WILTON, Stephen D. et al., "Specific removal of the nonsense mutation from the mdx dystrophin mRNA using antisense oligonucleotides," Neuromuscular Disorders, Vol. 9:330-338 (1999)	<input type="checkbox"/>
36	WO 2002/24906 A1 of AZL, (University of Western Australia Exhibit 2134, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-43.)	<input type="checkbox"/>
37	WO 2004/083432 (the published AZL PCT Application, "Van Ommen"), Pages 71, Exhibit Number 1003 filed in Interference 106,013 on February 17, 2015.	<input type="checkbox"/>
38	WO 2013/112053 A1, (University of Western Australia Exhibit 2130, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-177).	<input type="checkbox"/>
39	WOLFF, Jon A. et al., "Direct Gene Transfer into Mouse Muscle in Vivo," Science, Vol. 247:1465-1468 (1990)	<input type="checkbox"/>
40	WONG, Marisa L. et al., "Real-time PCR for mRNA quantitation," BioTechniques, Vol. 39:75-85 (2005) (Exhibit Number 1066 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
41	Wood, "Toward an Oligonucleotide Therapy for Duchenne Muscular Dystrophy: A Complex Development Challenge," Science Translational Medicine, Vol. 2, No. 25, pp. 1-6 (March, 2010), Exhibit Number 1116 filed in interferences 106,007 and 106,008 on February 17, 2015, Doc 335.	<input type="checkbox"/>
42	Written Opinion for Application No. PCT/AU2010/001520, 6 pages, dated January 21, 2011	<input type="checkbox"/>
43	WU, B. et al., "Dose-dependent restoration of dystrophin expression in cardiac muscle of dystrophic mice by systemically delivered morpholino," Gene Therapy, Vol. 17:132-140 (2010)	<input type="checkbox"/>
44	WU, Bo et al., "Effective rescue of dystrophin improves cardiac function in dystrophin-deficient mice by a modified morpholino oligomer," PNAS, Vol. 105(39):14814-14819 (2008)	<input type="checkbox"/>

**INFORMATION DISCLOSURE
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Attorney Docket Number	AVN-017

45	WU, Bo et al., "Targeted Skipping of Human Dystrophin Exons in Transgenic Mouse Model Systemically for Antisense Drug Development," PLoS One, Vol. 6(5):e19906, 11 pages (2011)	<input type="checkbox"/>
46	WU, George Y. et al., "Receptor-mediated Gene Delivery and Expression in Vivo," The Journal of Biological Chemistry, Vol. 263(29):14621-14624 (1988)	<input type="checkbox"/>
47	WU, George Y. et al., "Receptor-mediated in Vitro Gene Transformation by a Soluble DNA Carrier System," The Journal of Biological Chemistry, Vol. 262(10):4429-4432 (1987)	<input type="checkbox"/>
48	Wyatt et al. "Site-specific cross-linking of mammalian U5 snRNP to the 5' splice site before the first step of pre-mRNA splicing," Genes & Development, Vol. 6, pp. 2542-2553 (1992), Exhibit Number 1198 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
49	Yin et al., "A fusion peptide directs enhanced systemic dystrophin exon skipping and functional restoration in dystrophin-deficient mdx mice," Human Mol. Gen., Vol. 18, No. 22, pp. 4405-4414 (2009), Exhibit Number 1200 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
50	Yin et al., "Cell Penetrating peptide-conjugated antisense oligonucleotides restore systemic muscle and cardiac dystrophin expression and function," Human Mol. Gen., Vol. 17, No. 24, pp. 3909-3918 (2008), Exhibit Number 1199 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>

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1	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Reply 3 (for Judgment under 35 U.S.C. §135(b)) filed April 3, 2015 in Interference 106008, pages 1-19 (Doc 438).	<input type="checkbox"/>
2	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Reply 3 (to Institute an Interference) filed April 3, 2015 in Interference 106007, pages 1-17 (Doc 430).	<input type="checkbox"/>
3	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Reply 4 (To Exclude Evidence), filed in Patent Interference No. 106,007, May 12, 2015, pages 1-13 (Doc 467).	<input type="checkbox"/>
4	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Reply 4 (To Exclude Evidence), filed in Patent Interference No. 106,008, May 12, 2015, pages 1-13 (Doc 475).	<input type="checkbox"/>
5	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Request for Oral Argument, filed in Patent Interference No. 106,007, April 10, 2015, pages 1-4 (Doc 457).	<input type="checkbox"/>
6	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Request for Oral Argument, filed in Patent Interference No. 106,008, April 10, 2015, pages 1-4 (Doc 465).	<input type="checkbox"/>
7	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Request for Oral Argument, filed in Patent Interference No. 106,013, April 10, 2015, pages 1-3 (Doc 190).	<input type="checkbox"/>
8	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Revised Designation of Lead and Backup Counsel, 4 pages, Patent Interference No. 106,007, (Doc 415), dated March 10, 2015.	<input type="checkbox"/>
9	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Revised Designation of Lead and Backup Counsel, 4 pages, Patent Interference No. 106,013, (Doc 150), dated March 10, 2015.	<input type="checkbox"/>
10	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Revised Designation of Lead and Backup Counsel, 5 pages, Patent Interference No. 106,008, (Doc 423), dated March 10, 2015.	<input type="checkbox"/>
11	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia, Exhibit List as of February 17, 2015, 8 pages, Patent Interference No. 106,007, (Doc No. 398) dated February 17, 2015.	<input type="checkbox"/>

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12	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia, Exhibit List as of February 17, 2015, 8 pages, Patent Interference No. 106,008, (Doc No. 406) dated February 17, 2015.	<input type="checkbox"/>
13	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Clean Copy of Involved Claims and Sequence, Patent Interference No. 106,007, 8 pages, dated August 1, 2014 (Doc 12)	<input type="checkbox"/>
14	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Clean Copy of Involved Claims and Sequence, Patent Interference No. 106,013, 7 pages, dated October 14, 2014 (Doc 7)	<input type="checkbox"/>
15	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Clean Copy of Involved Claims and Sequences, Patent Interference No. 106,008, 8 pages, dated August 7, 2014 (Doc 12)	<input type="checkbox"/>
16	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Exhibit List as of November 18, 2014, 7 pages, Patent Interference No. 106,008, dated November 18, 2014 (Doc 216)	<input type="checkbox"/>
17	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Exhibit list, 7 pages, Patent Interference No. 106,007, dated November 18, 2014 (Doc 213)	<input type="checkbox"/>
18	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Exhibit list, 7 pages, Patent Interference No. 106,013, dated November 18, 2014 (Doc 134)	<input type="checkbox"/>
19	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Exhibit List, 7 pages, Patent Interference Nos. 106,008, dated December 12, 2014 (Doc 221)	<input type="checkbox"/>
20	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Exhibit List, 8 pages, Patent Interference No. 106,007, dated December 12, 2014 (Doc 217)	<input type="checkbox"/>
21	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA List of Proposed Motions, Patent Interference No. 106,007, 7 pages, dated September 10, 2014 (Doc 17)	<input type="checkbox"/>
22	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA List of Proposed Motions, Patent Interference No. 106,008, 6 pages, dated September 10, 2014 (Doc 16)	<input type="checkbox"/>

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23	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Miscellaneous Motion 1 (for authorization to file terminal disclaimer), 5 pages, Patent Interference No. 106,008, dated October 17, 2014 (Doc 22)	<input type="checkbox"/>
24	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Motion 1 (For Judgment Under 35 U.S.C., section 112(a)), 40 pages, Patent Interference No. 106,007, dated November 18, 2014 (Doc 210)	<input type="checkbox"/>
25	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Motion 1 (For Judgment Under 35 § 112(a)) Patent Interference No. 106,008 (Doc 213), 38 Pages, on November 18, 2014	<input type="checkbox"/>
26	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Motion 1 (To Maintain Interference between UWA US Patent No. 8,486,907 and AZL USSN 14/198,992), 45 pages, Patent Interference No. 106,013, dated November 18, 2014 (Doc 133)	<input type="checkbox"/>
27	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Motion 2 (For Judgment Under 35 U.S.C. section 112(b)), 32 pages, Patent Interference No. 106,008, dated November 18, 2014 (Doc 214)	<input type="checkbox"/>
28	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Motion 2 (For Judgment Under 35 U.S.C. section 112(b)), 34 pages, Patent Interference No. 106,007, dated November 18, 2014 (Doc 211)	<input type="checkbox"/>
29	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Motion 3 (For judgment that Claims 11-12, 14-15, and 17-29 of Application No. 13/550,210 are barred under 35 U.S.C. section 135(b)), 25 Pages, Patent Interference No. 106,008, dated November 18, 2014 (Doc 215)	<input type="checkbox"/>
30	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Motion 3 Requesting an additional Interference between UWA U.S. Patent No. 8,455,636 and AZL USSN 14/248,279, 36 pages, Patent Interference No. 106,007, dated November 18, 2014 (Doc 212)	<input type="checkbox"/>
31	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Filing Priority Statement, 2 pages, Patent Interference No. 106,007, dated November 18, 2014 (Doc 215)	<input type="checkbox"/>
32	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Filing Priority Statement, 2 pages, Patent Interference No. 106,008, dated November 18, 2014 (Doc 218)	<input type="checkbox"/>
33	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Recent Authority, filed in Patent Interference No. 106,007, July 2, 2015, pages 1-16 (Doc 469).	<input type="checkbox"/>

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34	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Recent Authority, filed in Patent Interference No. 106,007, September 2, 2015, pages 1-18 (Doc 470).	<input type="checkbox"/>
35	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Recent Authority, filed in Patent Interference No. 106,008, July 2, 2015, pages 1-16 (Doc 477).	<input type="checkbox"/>
36	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Recent Authority, filed in Patent Interference No. 106,008, September 2, 2015, pages 1-18 (Doc 478).	<input type="checkbox"/>
37	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Related Proceedings, Patent Interference No. 106,007, 3 pages, dated August 1, 2014 (Doc 11)	<input type="checkbox"/>
38	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Related Proceedings, Patent Interference No. 106,008, 5 pages, dated August 7, 2014 (Doc 11)	<input type="checkbox"/>
39	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Related Proceedings, Patent Interference No. 106,013, 3 pages, dated October 14, 2014 (Doc 6)	<input type="checkbox"/>
40	US 7,960,541 (Wilton et al.), Pages 84, Exhibit Number 1002 filed in interferences 106,007 and 106,008 on November 18, 2014.	<input type="checkbox"/>
41	US 8,450,474 (Wilton et al.), Pages 95, Exhibit Number 1087 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
42	US 8,455,634 (Wilton et al.) Pages 96, Exhibit Number 1088 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
43	US 8,455,635 (Wilton et al.), Pages 96, Exhibit Number 1089 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
44	US 8,455,636 (Wilton et al.), Pages 92, Exhibit Number 1003 filed in interferences 106,007 and 106,008 on November 18, 2014.	<input type="checkbox"/>

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45	US 8,476,423 (Wilton et al.), Pages 95, Exhibit Number 1111 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
46	US 8,501,703 (Bennett et al.), Pages 16, Exhibit Number 1090 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
47	US 8,501,704 (Mourich et al.), Pages 39, Exhibit Number 1091 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
48	US 8,524,676 (Stein et al.), Pages 28, Exhibit Number 1092 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
49	US 8,524,880 (Wilton et al.), Pages 89, Exhibit Number 1093 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
50	US 8,536,147 (Weller et al.), Pages 95, Exhibit Number 1094 filed in interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>

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1	Larsen et al., "Antisense properties of peptide nucleic acid," Biochim. Et Biophys. Acta, Vol. 1489, pp. 159-166 (1999), Exhibit Number 1190 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
2	List of Publications for Matthew J. A. Wood, M.D., D. PHIL., 11 pages, (Exhibit Number 2124 filed in interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
3	LIU, Hong-Xiang et al., "Identification of functional exonic splicing enhancer motifs recognized by individual SR proteins," Genes & Development, Vol. 12:1998-2012 (1998)	<input type="checkbox"/>
4	Lu et al, "Massive Idiosyncratic Exon Skipping Corrects the Nonsense Mutation in Dystrophic Mouse Muscle and Produces Functional Revertant Fibers by Clonal Expansion," THE JOURNAL OF CELL BIOLOGY, Vol. 148(5): 985-995, March 6, 2000 ("Lu et al.") (Exhibit Number 1082 filed in interferences 106008, 106007 on December 23, 2014)	<input type="checkbox"/>
5	LU, Qi Long et al., "Functional amounts of dystrophin produced by skipping the mutated exon in the mdx dystrophic mouse," Nature Medicine, Vol. 9(8):1009-1014 (2003)	<input type="checkbox"/>
6	LU, Qi-long et al., "What Can We Learn From Clinical Trials of Exon Skipping for DMD?" Molecular Therapy - Nucleic Acids, Vol. 3:e152, doi:10.1038/mtna.2014.6, 4 pages (2014)	<input type="checkbox"/>
7	Lyophilisation of Oligonucleotides, Pages 2, Exhibit Number 1133 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
8	MANN, Christopher J. et al., "Antisense-induced exon skipping and synthesis of dystrophin in the mdx mouse," PNAS, Vol. 98(1):42-47 (2001)	<input type="checkbox"/>
9	MANN, Christopher J. et al., "Improved antisense oligonucleotide induced exon skipping in the mdx mouse model of muscular dystrophy," The Journal of Gene Medicine, Vol. 4:644-654 (2002)	<input type="checkbox"/>
10	MANNINO, Raphael J. et al., "Liposome Mediated Gene Transfer," BioTechniques, Vol. 6(7):682-690 (1988)	<input type="checkbox"/>
11	Manual of Patent Examining Procedure 2308.02 (6th ed., rev. 3, July 1997), (University of Western Australia Exhibit 2143, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-2).	<input type="checkbox"/>

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12	Manzur A, et al., "Glucocorticoid corticosteroids for Duchenne muscular dystrophy," Cochrane Database Syst Rev. 2004;(2):CD003725.	<input type="checkbox"/>
13	MARSHALL, N.B. et al., "Arginine-rich cell-penetrating peptides facilitate delivery of antisense oligomers into murine leukocytes and alter pre-mRNA splicing," Journal of Immunological Methods, Vol. 325:114-126 (2007)	<input type="checkbox"/>
14	Mathews et al., "Expanded Sequence Dependence of Thermodynamic Parameters Improves Prediction of RNA Secondary Structure," J. Mol. Biol. 288:911-940 (1999), (University of Western Australia Exhibit 2131, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-31).	<input type="checkbox"/>
15	Mathews et al., "Expanded Sequence Dependence of Thermodynamic Parameters Improves Prediction of RNA Secondary Structure," J. Mol. Biol., Vol. 288, pp. 911-940 (1999), Exhibit Number 1212 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
16	MATSUO, Masafumi et al., "Exon Skipping during Splicing of Dystrophin mRNA Precursor due to an Intraexon Deletion in the Dystrophin Gene of Duchenne Muscular Dystrophy Kobe," J. Clin. Invest., Vol. 87:2127-2131 (1991)	<input type="checkbox"/>
17	MATSUO, Masafumi et al., "Treatment of Duchenne Muscular Dystrophy with Oligonucleotides against an Exonic Splicing Enhancer Sequence," Basic Appl. Myol., Vol. 13(6):281-285 (2003)	<input type="checkbox"/>
18	MATSUO, Masafumi, "Duchenne and Becker Muscular Dystrophy: From Gene Diagnosis to Molecular Therapy," IUBMB Life, Vol. 53:147-152 (2002)	<input type="checkbox"/>
19	MATSUO, Masafumi, "Duchenne/Becker muscular dystrophy: from molecular diagnosis to gene therapy," Brain & Development, Vol. 18:167-172 (1996)	<input type="checkbox"/>
20	MATTEUCCI, Mark, "Structural modifications toward improved antisense oligonucleotides," Perspectives in Drug Discovery and Design, Vol. 4:1-16 (1996)	<input type="checkbox"/>
21	Mazzone E, et al. "Functional changes in Duchenne muscular dystrophy: a 12-month longitudinal cohort study," Neurology 2011;77(3):250-6.	<input type="checkbox"/>
22	MCCARVILLE, M. Beth et al., "Rhabdomyosarcoma in Pediatric Patients: The Good, the Bad, and the Unusual," AJR, Vol. 176:1563-1569 (2001) (Exhibit Number 1034 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>

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23	McCLOREY, G. et al., "Antisense oligonucleotide-induced exon skipping restores dystrophin expression in vitro in a canine model of DMD," Gene Therapy, Vol. 13:1373-1381 (2006)	<input type="checkbox"/>
24	McCLOREY, G. et al., "Induced dystrophin exon skipping in human muscle explants," Neuromuscular Disorders, Vol. 16:583-590 (2006)	<input type="checkbox"/>
25	McCLOREY, Graham et al., "Splicing intervention for Duchenne muscular dystrophy," Current Opinion in Pharmacology, Vol. 5:529-534 (2005)	<input type="checkbox"/>
26	McDonald CM, et al., "Profiles of Neuromuscular Diseases, Duchenne muscular dystrophy," Am J Phys Med Rehabil 1995;74:S70-S92	<input type="checkbox"/>
27	McDonald CM, et al., "The 6-minute walk test as a new outcome measure in Duchenne muscular dystrophy," Muscle Nerve 2010;41:500-10.	<input type="checkbox"/>
28	McDonald CM, et al., "The 6-minute walk test in Duchenne/Becker muscular dystrophy: longitudinal observations," Muscle Nerve 2010;42: 966-74.	<input type="checkbox"/>
29	Mendell JR et al., "Evidence-based path to newborn screening for Duchenne muscular Dystrophy," Ann Neurol 2012;71:304-13.	<input type="checkbox"/>
30	Mendell JR, et al., "Dystrophin immunity revealed by gene therapy in Duchenne muscular dystrophy," N Engl J Med 2010;363:1429-37.	<input type="checkbox"/>
31	Mendell JR, et al., "Randomized, double-blind six-month trial of prednisone in Duchenne's muscular dystrophy," N Engl J Med 1989;320:1592-97.	<input type="checkbox"/>
32	MENDELL, Jerry R. et al., "Eteplirsen for the Treatment of Duchenne Muscular Dystrophy," Ann. Neurol., Vol. 74:637-647 (2013) (Exhibit Number 2058 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
33	MENDELL, Jerry R. et al., "Eteplirsen in Duchenne Muscular Dystrophy (DMD): 144 Week Update on Six-Minute Walk Test (6MWT) and Safety," slideshow, presented at the 19th International Congress of the World Muscle Society, 17 pages (2014) (Exhibit Number 2059 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /DS/

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	14213641
Filing Date	2014-03-14
First Named Inventor	Richard K. BESTWICK
Art Unit	1674
Examiner Name	D. H. Shin
Attorney Docket Number	AVN-017

34	MENDELL, Jerry R. et al., "Gene therapy for muscular dystrophy: Lessons learned and path forward," Neuroscience Letters, Vol. 527:90-99 (2012)	<input type="checkbox"/>
35	Merlini L, et al., "Early corticosteroid treatment in 4 Duchenne muscular dystrophy patients: 14-year follow-up," Muscle Nerve 2012;45:796-802.	<input type="checkbox"/>
36	Mfold illustrations for Exon 51 and Exon 53 with varying amounts of intron sequence, (University of Western Australia Exhibit 2132, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-2).	<input type="checkbox"/>
37	MITRPANT, Chalermchai et al., "Rational Design of Antisense Oligomers to Induce Dystrophin Exon Skipping," Molecular Therapy, Vol. 17(8):1418-1426 (2009)	<input type="checkbox"/>
38	MONACO, Anthony P. et al., "An Explanation for the Phenotypic Differences between Patients Bearing Partial Deletions of the DMD Locus," Genomics, Vol. 2:90-95 (1988)	<input type="checkbox"/>
39	Morcos, Paul A., "Gene switching: analyzing a broad range of mutations using steric block antisense oligonucleotides," Methods in Enzymology, Vol. 313:174-189 (1999)	<input type="checkbox"/>
40	MOULTON, H.M., "Compound and Method for Treating Myotonic Dystrophy," U.S. Application No. 12/493,140, 82 pages, filed June 26, 2009	<input type="checkbox"/>
41	MOULTON, Hong M. et al., "Morpholinos and their peptide conjugates: Therapeutic promise and challenge for Duchenne muscular dystrophy," Biochimica et Biophysica Acta, Vol. 1798:2296-2303 (2010)	<input type="checkbox"/>
42	Muntoni F, et al., "Dystrophin and mutations: one gene, several proteins, multiple phenotypes," Lancet Neurol. 2003;2:731-40.	<input type="checkbox"/>
43	MUNTONI, Francesco et al., "128th ENMC International Workshop on 'Preclinical optimization and Phase I/II Clinical Trials Using Antisense Oligonucleotides in Duchenne Muscular Dystrophy' 22-24 October 2004, Naarden, The Netherlands," Neuromuscular Disorders, Vol. 15:450-457 (2005) (Exhibit Number 2025 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
44	MUNTONI, Francesco et al., "149th ENMC International Workshop and 1st TREAT-NMD Workshop on: 'Planning Phase I/II Clinical trials using Systemically Delivered Antisense Oligonucleotides in Duchenne Muscular Dystrophy,'" Neuromuscular Disorders, Vol. 18:268-275 (2008)	<input type="checkbox"/>

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /DS/

**INFORMATION DISCLOSURE
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(Not for submission under 37 CFR 1.99)

Application Number	14213641
Filing Date	2014-03-14
First Named Inventor	Richard K. BESTWICK
Art Unit	1674
Examiner Name	D. H. Shin
Attorney Docket Number	AVN-017

45	NELSON, David L. et al., "Nucleotides and Nucleic Acids," Lehninger Principles of Biochemistry, 3rd Edition, Chapter 10, pages 325-328 and glossary page G-11, Worth Publishers, New York (2000)	<input type="checkbox"/>
46	Nguyen TM, et. Al., "Use of Epitope libraries to identify exon-specific monoclonal antibodies for characterization of altered dystrophins in muscular dystrophy," Am J Hum Genet 1993;52:1057-66.	<input type="checkbox"/>
47	Oberbauer, "Renal uptake of an 18-mer phosphorothioate oligonucleotide," Kidney Int'l, Vol. 48, pp. 1226-1232 (1995), Exhibit Number 1191 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
48	Oligonucleotide Cleavage and Deprotection Laboratory Notebook Entry, Pages 1, Exhibit Number 1138 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
49	Oligonucleotide diagrams, 5 pages (Exhibit Number 1053 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
50	Partial European Search Report for Application No. 10004274.6, 6 pages, dated October 2, 2012	<input type="checkbox"/>

If you wish to add additional non-patent literature document citation information please click the Add button **Add**

EXAMINER SIGNATURE

Examiner Signature	/Dana Shin/	Date Considered	10/13/2015
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/213,641	03/14/2014	Richard K. BESTWICK	AVN-010A	7957

123147 7590 03/31/2015
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

EXAMINER

SHIN, DANA H

ART UNIT	PAPER NUMBER
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1674

NOTIFICATION DATE	DELIVERY MODE
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03/31/2015

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Please find below and/or attached an Office communication concerning this application or proceeding.

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chris.schlauch@nelsonmullins.com
ipqualityassuranceboston@nelsonmullins.com

Application No.
14/213,641
38271Applicant(s)
BESTWICK ET AL.**Office Action Summary**Examiner
DANA SHINArt Unit
1674AIA (First Inventor to File)
Status
No**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3-18-2015.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 1-4, 16-21, 33-38 and 44-59 is/are pending in the application.
 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-4, 16-21, 33-38 and 44-59 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 3-14-2014 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
 Paper No(s)/Mail Date ____.
- 3) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date ____.
- 4) ☐ Other: ____.

Application/Control Number: 14/213,641
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DETAILED ACTION

The present application is being examined under the pre-AIA first to invent provisions.

Election/Restrictions

Applicant's election without traverse of claims 1-39 and 42-43 with species election of SEQ ID NO:1 in the reply filed on March 18, 2015 is acknowledged.

Status of Claims

Claims 1-4, 16-21, 33-38, and 44-59 are pending and under examination on the merits in the instant case.

Information Disclosure Statement

The information disclosure statements submitted on March 18, 2015 have been considered by the examiner, except the information pertaining to AU 2003284638 A1 since applicant did not submit legible copies of the reference. Note that applicant merely submitted the cover page only. Further, JP2008507577 is not considered because the entire reference is in non-English language. In addition, non-English language references such as JP 2000-325085, JP2014138589, WO 2004/048570, WO 2006/021724, and WO 2013/100190 are considered only insofar as the English title and abstract.

Claim Rejections - 35 USC § 112

The following is a quotation of 35 U.S.C. 112(b):

(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

Application/Control Number: 14/213,641
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The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 16-21, 33-38, and 44-53 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

Claims 19, 51, and their dependent claims recite target regions in terms of which appears to be nucleotide positions. The recitation of target regions by nucleotide positions without specifically pointing out the target SEQ ID NO renders the claims indefinite because the nucleotide positions are not unchanging, definitive information as nucleotide sequences are constantly updated and there are nucleotide sequence variations.

For examination purpose, the recited regions will be interpreted as the nucleotide sequences targeted by SEQ ID NOs:1, 9, 11, and 15-18 in view of the specification.

Claims 1-4, 16-21, 33-38, and 44-53 are drawn to an antisense oligonucleotide of at least 20 or 25 nucleotides in length comprising SEQ ID NO:1. It is noted that SEQ ID NO:1 is 28 nucleotides in length. As such, it is impossible to make a 20-mer or a 25-mer oligonucleotide comprising the 28-mer sequence. Hence, the claims recite structurally conflicting limitations, thereby rendering the claims indefinite.

For examination purpose, the claims will be interpreted as an antisense oligonucleotide of at least 20 nucleotides in length comprising at least 20 consecutive nucleotides of SEQ ID NOs:1, 9, 11, and 15-18.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of pre-AIA 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 16-21, 33-38, and 44-59 are rejected under pre-AIA 35 U.S.C. 102(a) and 102(e) as being anticipated by Popplewell et al. (US 2012/0065244 A1).

Popplewell et al. disclose a 30-mer PMO antisense oligonucleotide SEQ ID NO:22, which comprises SEQ ID NO:1 claimed in the instant case.

Popplewell et al. teach that the oligonucleotide of SEQ ID NO:10 (corresponding to SEQ ID NO:22) can be 25, 26, 27, 28, 29, and 30 nucleotides in length, wherein X is T or U. See paragraphs 0014, 0027.

Popplewell et al. teach that the oligonucleotide is formulated as a pharmaceutical composition comprising pharmaceutically acceptable carrier or polyethylene glycol or “an arginine-rich cell penetrating peptide (CPP)” or an expression vector such as “an adeno-associated virus (AVV) vector”. See paragraphs 0032-0035.

Accordingly, all claim limitations are taught by Popplewell et al.

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Claims 1-3, 16-19, 21, 33-35, 44-45, and 47-53 are rejected under pre-AIA 35 U.S.C. 102(e) as being anticipated by De Visser et al. (US 2015/0045413 A1).

De Visser et al. disclose a 30-mer oligonucleotide SEQ ID NO:135 comprising SEQ ID NO:1, wherein T is replaced by U.

De Visser et al. teach that the oligonucleotide comprises morpholino phosphorodiamidate, 5-methylcytosine, and 2,6-diaminopurine. See paragraphs 0047, 0053, 0059-0065.

De Visser et al. teach that the oligonucleotide is formulated as a pharmaceutical composition comprising a pharmaceutically acceptable carrier/excipient such as polyethylene glycol and polyarginine. See paragraphs 0641-0643.

Accordingly, all claim limitations are taught by De Visser et al.

Claims 1-3, 16-21, 33-38, and 44-53 are rejected under pre-AIA 35 U.S.C. 102(b) as being anticipated by Sazani et al. (WO 2010/048586 A1, applicant's citation).

Sazani et al. disclose a 30-mer PMO antisense oligonucleotide SEQ ID NO:631 that induces human dystrophin exon 53 skipping, wherein the oligonucleotide comprises at least 20 consecutive nucleotides of SEQ ID NO:1 claimed in the instant case.

Sazani et al. teach that the oligonucleotide can be 20-35 nucleotides in length. See claim 36.

Sazani et al. teach that the oligonucleotide comprises 5-methylcytidine or 2-methylthio-N6-isopentenyladenosine. See page 19.

Sazani et al. teach that "the T bases may be shown as U". See page 20.

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Sazani et al. teach that the oligonucleotide is “conjugated to an arginine-rich polypeptide” or chemically linked to a polyethyleneglycol to promote uptake of the compound into cells. See pages 8-10.

Sazani et al. teach that the oligonucleotide is formulated as a pharmaceutical composition comprising one or more pharmaceutically acceptable carriers. See page 45.

Sazani et al. teach a kit comprising the oligonucleotide “packaged in a suitable container and instruction for its use.” See page 12.

Sazani et al. teach that the oligonucleotide can be delivered via an expression vector such as an adeno-associated viral vector or retroviral vector. See pages 30-31.

Accordingly, all claim limitations are taught by Sazani et al.

Claims 1-3, 16, 18-19, 21, 33, 35-36, 44-45, and 47-53 are rejected under pre-AIA 35 U.S.C. 102(b) as being anticipated by Wilton et al. (WO 2011/057350 A1, applicant’s citation).

Wilton et al. disclose an antisense oligonucleotide that induces exon 53 skipping and anneals to the target region +33+63 (thus necessarily encompassing +33+60 and +33+57) in Table 43 as below:

H53A(+33+63) | ACU GUU GCC UCC GGU UCU GAA GGU GUU CUU G

Wilton et al. teach that the antisense oligonucleotide comprises “phosphoromorpholidates, phosphoropiperazidates and phosphoramidates”, “N-2, N-6 and O-6 substituted purines”, and 5-methylcytosine substitutions and is chemically linked to “one or more moieties or conjugates that enhance the activity, cellular distribution or cellular uptake of the oligonucleotide.” See pages 24-25. They teach that the moieties comprise “a polyamine or a polyethylene glycol chain”. See page 25.

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Wilton et al. teach that the oligonucleotide is expressed from an expression vector. See page 29.

Wilton et al. teach that the antisense oligonucleotide is formulated as a pharmaceutical composition with a pharmaceutically acceptable carrier thus is useful for therapy and can be prepared as a kit. See pages 28-32.

Accordingly, all claim limitations are taught by Wilton et al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope

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of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit <http://www.uspto.gov/forms/>. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to <http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp>.

Claims 1, 19-20, 48, and 51 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-32 of U.S. Patent No. 8,779,128 B2.

Although the claims at issue are not identical, they are not patentably distinct from each other because the instant claims are anticipated by the '128 patent claims. Note that the "oligomer" of the '128 patent claims necessarily encompasses SEQ ID NO:34 disclosed in the '128 specification, which defines that the oligomer is one of SEQ ID NOs:1-55 disclosed in Table 11, wherein SEQ ID NO:34 comprises at least 20 consecutive nucleotides of SEQ ID NO:11. Note that "those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent." See MPEP §804. See also *Pfizer Inc. v. Teva Pharmaceuticals USA Inc.*, 518 F.3d 1353, 86 USPQ2d 1001 (Fed. Cir. 2008), wherein the court expressed the following: "To the extent that Pfizer contends that we may not rely on the teachings of the specification or claims in the '165 patent to reject the claims of the '068 patent, we disagree. *See Geneva*, 349 F.3d at 1386. There is nothing that prevents us from looking to the specification to determine the proper scope of the claims."

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Page 9

Claims 1-3, 16-21, 33-38, and 44-59 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-32 of U.S. Patent No. 8,779,128 B2 in view of Popplewell et al. (US 2012/0065244 A1).

Although the claims at issue are not identical, they are not patentably distinct from each other because the instant claims are an obvious variation of the '128 patent claims in view of Sazani et al. It would have been obvious to one of ordinary skill in the art to use Popplewell's SEQ ID NO:10 as the oligomer of the '128 patent claims because it was an art-recognized goal to make a morpholino-modified oligomer that induces dystrophin exon 53 skipping as taught by Popplewell et al. Hence, the instant claims are an obvious variation of the '128 patent claims.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANA SHIN whose telephone number is (571)272-8008. The examiner can normally be reached on Monday through Thursday, 7am-5:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 14/213,641
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Page 10

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Dana Shin
Primary Examiner
Art Unit 1674

/DANA SHIN/
Primary Examiner, Art Unit 1674



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/213,641	03/14/2014	Richard K. BESTWICK	AVN-010A	7957
123147	7590	09/18/2014		
Nelson Mullins Riley & Scarborough LLP/Sarepta One Post Office Square Boston, MA 02109			EXAMINER SHIN, DANA H	
			ART UNIT 1674	PAPER NUMBER
			NOTIFICATION DATE 09/18/2014	DELIVERY MODE ELECTRONIC

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The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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chris.schlauch@nelsonmullins.com
ipqualityassuranceboston@nelsonmullins.com

Application No.
14/213,641
30282Applicant(s)
BESTWICK ET AL.**Office Action Summary**Examiner
DANA SHINArt Unit
1674AIA (First Inventor to File)
Status
No**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

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- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
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Status

- 1) ☒ Responsive to communication(s) filed on 3-14-2014.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 1-43 is/are pending in the application.
 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☐ Claim(s) ____ is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☒ Claim(s) 1-43 are subject to restriction and/or election requirement.

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Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
 Paper No(s)/Mail Date ____.
- 3) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date ____.
- 4) ☐ Other: ____.

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DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-39 and 42-43, drawn to an antisense oligonucleotide that induces human dystrophin exon 53 skipping, classified in CPC class C12N 15/113.

II. Claim 40, drawn to a method of treating DMD, classified in A61K 38/00.

III. Claim 41, drawn to use of an antisense molecule for manufacture of a medicament, classified in A61J 3/00.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and III are directed to related processes. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have different functions and effects. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions I and II-III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP

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§ 806.05(h). In the instant case the antisense oligonucleotide of group I can be used as a probe or primer.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and/or examination burden if restriction were not required because one or more of the following reasons apply:

- 1) the inventions have acquired a separate status in the art in view of the different classification;
- 2) the inventions require a different field of search (for example, searching different classes/subclasses or electronic sources, or employing different search queries);
- 3) the prior art applicable to one invention would not likely to be applicable to another invention;
- 4) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to

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petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 or pre-AIA 35 U.S.C. 103(a) of the other invention.

Election of Species

This application contains claims directed to the following patentably distinct species SEQ ID NOs:1, 9, 11, 15, 16, 17, and 18. The species are independent or distinct because they are materially different. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, or a single grouping of patentably indistinct species, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 19 are generic.

There is a search and/or examination burden for the patentably distinct species as set forth above because at least the following reason(s) apply:

- 1) the species require a different field of search (for example, employing different search queries);
- 2) the prior art applicable to one species would not likely to be applicable to another species;

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3) the species are likely to raise different non-prior art issues under 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species or grouping of patentably indistinct species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species or grouping of patentably indistinct species.

Should applicant traverse on the ground that the species, or groupings of patentably indistinct species from which election is required, are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing them to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 or pre-AIA 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be corrected in compliance with 37 CFR 1.48(a) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. A request to correct inventorship under 37 CFR 1.48(a) must be accompanied by an application data sheet in accordance with 37 CFR 1.76 that identifies each inventor by his or her legal name and by the processing fee required under 37 CFR 1.17(i).

Notice of Rejoinder

The examiner has required restriction between product or apparatus claims and process claims. Where applicant elects claims directed to the product/apparatus, and all product/apparatus claims are subsequently found allowable, withdrawn process claims that include all the limitations of the allowable product/apparatus claims should be considered for rejoinder. All claims directed to a nonelected process invention must include all the limitations of an allowable product/apparatus claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product/apparatus claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product/apparatus are found allowable, an otherwise proper restriction requirement between product/apparatus claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product/apparatus claim will not be rejoined. See MPEP § 821.04. Additionally, in order for rejoinder to occur, applicant is advised that the process claims should be amended

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during prosecution to require the limitations of the product/apparatus claims. **Failure to do so may result in no rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANA SHIN whose telephone number is (571)272-8008. The examiner can normally be reached on Monday through Thursday, 7am-5:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Babic can be reached on 571-272-8507. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin
Primary Examiner
Art Unit 1674

/DANA SHIN/
Primary Examiner, Art Unit 1674



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/214,480	03/14/2014	Richard K. Bestwick	AVN-013BRCE	3826

123147 7590 08/02/2016
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

EXAMINER

SHIN, DANA H

ART UNIT	PAPER NUMBER
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1674

NOTIFICATION DATE	DELIVERY MODE
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08/02/2016

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipboston.docketing@nelsonmullins.com
chris.schlauch@nelsonmullins.com
ipqualityassuranceboston@nelsonmullins.com

Application No.
14/214,480
#: 58290Applicant(s)
BESTWICK ET AL.**Office Action Summary**Examiner
DANA SHINArt Unit
1674AIA (First Inventor to File)
Status
No**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2-18-2016.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 16 and 22-27 is/are pending in the application.
 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 16 and 22-27 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
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 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
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 Paper No(s)/Mail Date ____.
- 4) ☐ Other: ____.

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DETAILED ACTION

The present application is being examined under the pre-AIA first to invent provisions.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 18, 2016 has been entered.

Status of Claims

Claims 16 and 22-27 are currently pending and under examination on the merits in the instant case.

Claim Rejections - 35 USC § 103

The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under pre-AIA 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to

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point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of pre-AIA 35 U.S.C. 103(c) and potential pre-AIA 35 U.S.C. 102(e), (f) or (g) prior art under pre-AIA 35 U.S.C. 103(a).

Claims 16 and 22-27 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Sazani et al. (WO 2010/048586 A1, of record) in view of Hanson (US 2012/0289457 A1, of record), Platenburg et al. (US 2012/0059042 A1, applicant's citation), Wilton et al. (US 2008/0200409 A1, applicant's citation), and Harding et al. (*Molecular Therapy*, 2007, 15:157-166, of record).

Sazani discloses 20 antisense oligonucleotides (SEQ ID NOs:1-20) scanned for skipping exon 44 of human DMD. See page 79.

Sazani discloses that five exon 44 skipping PMO sequences (SEQ ID NOs:4, 8, 11, 12, and 13) are "selected as being most active in the exon 44 scan." See pages 14, 76-77.

Sazani discloses SEQ ID NO:4 as below:

Hu.DMD.Exon44.25.004 | GATCTGTCAAATCGCCTGCAGGTAA
----- SEQ ID NO:4
----- SEQ ID NO:5
----- SEQ ID NO:6

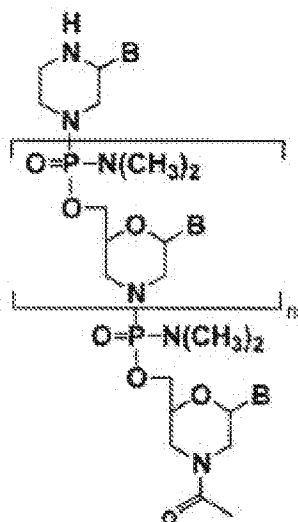
The above sequence comprises the entire 23-mer sequence of SEQ ID NO:4, the entire 22-mer sequence of SEQ ID NO:5, and the entire 21-mer sequence of SEQ ID NO:6 claimed in the instant case as indicated above.

Sazani teaches that exon skipping morpholino antisense oligonucleotides can be "20-35" nucleotides in length such as 20, 21, and 22 nucleotides in length complementary to dystrophin exon 44. See claim 1 and page 41.

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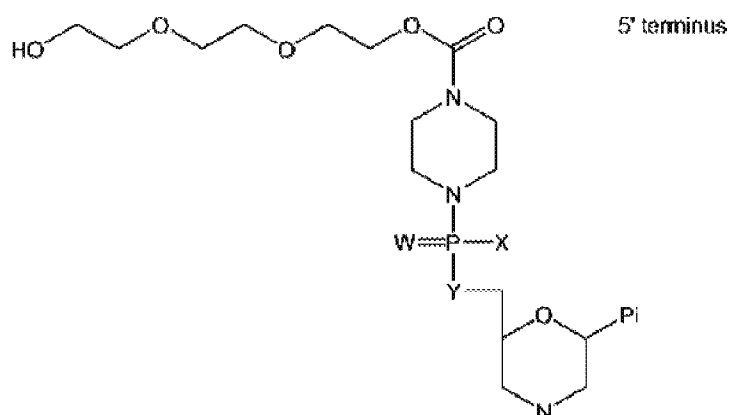
Page 4

Sazani teaches that the intersubunit linkage has the structure shown in Figure 1A as below:



Sazani teaches making a composition comprising the antisense oligonucleotide and a pharmaceutically acceptable carrier. See page 46.

Hanson teaches making an exon skipping PMO antisense oligonucleotide comprising a 5' terminus triethylene glycol ("EG3") linked to the PMO via a piperazine linker as shown in Figure 1C as below:

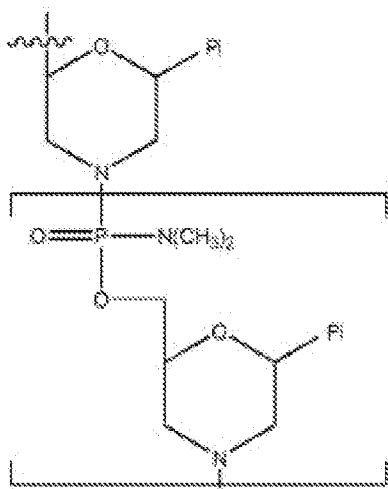


See also paragraphs 0478-0483; Table 7.

Hanson's above structure has $N(CH_3)_2$ in place of "X" as evidenced by Figure 1A as below:

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Hanson discloses three exon 44 skipping antisense oligonucleotides of SEQ ID NOs:22-24, wherein SEQ ID NO:22 is identical to Sazani's SEQ ID NO:4. See Table 1 at page 25.

Platenburg teaches that one can make exon skipping oligonucleotides that are 20-26 nucleotides in length having a significant level of sequence homology of a minimum of about 77% and a maximum of about 95%, wherein all oligonucleotides have the same 20-mer sequence and are different only in the 3' region. See Table 1 disclosing the 20-mer SEQ ID NO:5 as well as a 21-mer SEQ ID NO:8, a 22-mer SEQ ID NO:12, a 23-mer SEQ ID NO:14, a 24-mer SEQ ID NO:16, a 25-mer SEQ ID NO:18, and a 26-mer SEQ ID NO:20.

Platenburg demonstrates that SEQ ID NO:45 (19-mer "PS 187") and SEQ ID NO:46 (23-mer "PS 194") sharing the same 19-mer are effective in inducing exon 44 skipping, wherein "PS 187" induces 72% skipping and "PS 194" induces 87% skipping. See Figures 1a and 1b. See the sequences in Table 1 as below:

41 (PS 187)	GCCAUFUCUCAACAGAUUU	SEQ ID NO 45
42 (PS 194)	GCCAUFUCUCAACAGAUUCUGUCA	SEQ ID NO 46

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Wilton demonstrates that antisense oligonucleotides of 21-mer, 24-mer, and 25-mer having the same 21-mer sequence are effective in inducing exon skipping. See the three nucleotide sequences in Table 2 as below:

TABLE 2

Anti-sense Oligonucleotide name	Sequence	Ability to induce skipping
H8A (-06 + 18)	5'-GAU AGG UCG UAU CAA CAU CUG UAA	Very strong to 20 nM
H8A (-03 + 18)	5'-GAU AGG UCG UAU CAA CAU CUG	Very strong skipping to 40 nM
H8A (-07 + 18)	5'-GAU AGG UCG UAU CAA CAU CUG UAA G	Strong skipping to 40 nM

Harding teaches that exon skipping antisense oligonucleotides can be as short as 20 nucleotides, which are capable of inducing exon skipping as 25-mers that comprise the entire 20-mer sequence of the 20-mer antisense oligonucleotide. See “M23D(+07-18)” and “M23D(+02-18)” in Table 1 as below:

M23D(+07-18)	GGC CAA ACC UCG GCU UAC CUG AAA U
M23D(+02-18)	GGC CAA ACC UCG GCU UAC CU

Harding reports that the “20 and 25mers, M23D(+07-18) and M23D(+02-18), induced similar levels of murine dystrophin exon 23 skipping after *in vitro* transfection at concentrations of 200 nM or higher.” See page 160.

Regarding the oligomers of SEQ ID NOs:4, 5, and 6 and pharmaceutical compositions comprising thereof, one of ordinary skill in the art would have been motivated at the time the invention was made, with a reasonable expectation of success, to shorten the length of Sazani's

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25-mer SEQ ID NO:4 or Hanson's SEQ ID NO:22 to oligomers of 21, 22, and 23 nucleotides in length by truncating the 3' end region of the prior art's PMO sequence so as to more economically synthesize dystrophin exon 44 skipping oligonucleotides at a reduced synthesis cost as compared to the cost of producing a 25-mer oligonucleotide, because it was known to synthesize dystrophin exon skipping oligonucleotides of 21, 22, and 23 nucleotides in length as taught by Sazani et al. (see claim 1 and page 41), Platenburg (see a 21-mer SEQ ID NO:8, a 22-mer SEQ ID NO:12, a 23-mer SEQ ID NO:14, and 23-mer "PS 194"), and Wilton (see 21-mer "H8A(-03+18)"), and because 3' end-truncated oligonucleotides of shorter lengths (e.g., 19-mer, 20-mer, 21-mer, and 24-mer) were known to be as effective as longer oligonucleotides (e.g., 25-mer) in inducing dystrophin exon skipping as demonstrated by Platenburg, Wilton, and Harding.

In addition, since Sazani provided only a finite number of five identified, predictable active exon 44 skipping oligonucleotides, wherein the selection of Sazani's SEQ ID NO:4 is further corroborated by Hanson's SEQ ID NO:22 further comprising a 5' terminus triethylene glycol ("EG3") linked to the PMO via a piperazine linker, and since the exon skipping oligonucleotides sharing a significant nucleotide sequence homology level with a slight difference in the 3' end region by a few nucleotides were reasonably predicted to retain exon skipping activity as evidenced by Platenburg, Wilton, and Harding, one of ordinary skill in the art would have reasonably pursued the prior art's PMO to synthesize shorter PMOs as done by Platenburg, who exemplifies exon skipping oligonucleotides of a 21-mer SEQ ID NO:8, a 22-mer SEQ ID NO:12, a 23-mer SEQ ID NO:14, a 24-mer SEQ ID NO:16, and a 25-mer SEQ ID NO:18, all of which comprise the same 21-mer sequence in the 5' region and differ only in the 3' region.

"When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue

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the known options within his or her technical grasp. If this leads to the anticipated success, it is likely that not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421, 82 USPQ2d 1385, 1397 (2007).

Accordingly, claims 16 and 21-27 taken as a whole would have been *prima facie* obvious at the time of the invention.

Response to Arguments

Applicant's arguments filed on February 18, 2016 have been fully considered but they are not persuasive. Applicant argues that the claims are not obvious because there is no motivation to pick Sazani's SEQ ID NO:4 as a lead compound to modify.

Regarding applicant's "lead compound" arguments, it is noted that applicant's selected "lead compound" analysis is not required in all chemical compound cases. See MPEP §2143: The Federal Circuit in *Eisai* makes it clear that from the perspective of the law of obviousness, **any known compound might possibly serve as a lead compound...**It should be noted that the **lead compound cases do not stand for the proposition that identification of a single lead compound is necessary in every obviousness rejection of a chemical compound.**" (emphasis added). As such, there is no *per se* rule that requires a selection of a single lead compound for obviousness under §103.

Applicant argues that the claims are not obvious because there is no reason to shorten Sazani's SEQ ID NO:4. Contrary to applicant's argument, there is an economical reason to shorten the oligonucleotide length as set forth in the rejection. The Federal Circuit has recognized that "an implicit motivation to combine exists not only when a suggestion may be gleaned from the prior art as a whole, but when the "improvement" is technology-independent

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and the combination of references results in a product or process that is more desirable, for example because it is stronger, **cheaper**, cleaner, faster, lighter, smaller, more durable, or more efficient.” (emphasis added). See *DyStar Textilfarben GmbH & Co. Deutschland KG v. C. H. Patrick Co.*, 464 F.3d 1356, 1368 (Fed. Cir. 2006).

Applicant further argues that there is “a significant level of unpredictability” associated with antisense activity. It is not unreasonable to anticipate unpredictability in exon skipping activity of untested oligonucleotides. However, the instantly claimed oligonucleotide sequences do not deviate significantly from the prior art's 25-mer oligonucleotide sequence shown to have exon 44 skipping activity. For instance, SEQ ID NOs:4-6 have 92%, 88%, and 84% sequence homology with the prior art's 25-mer oligonucleotide, respectively, as all three nucleotide sequences of SEQ ID NOs:4-6 claimed in the instant case share the same 21-mer within the prior art's 25-mer exon 44 skipping oligonucleotide. It is amply suggested in the art that one of ordinary skill in the art can reasonably predict that exon skipping activity would be retained for oligonucleotides having a substantial sequence homology and differ by 2, 3, or 4 nucleotides only in the 3' end region in view of the experimental results demonstrated by Platenburg, Wilton, and Harding. As such, applicant's alleged high unpredictability level does not apply to the instantly claimed oligonucleotides that are only 2-nt, 3-nt, and 4-nt shorter, truncated sequence variations of the prior art's 25-mer oligonucleotide, wherein making exon skipping oligonucleotides of about 20-25 nucleotides in length sharing a significant sequence homology was known in the art as disclosed by Platenburg and a shorter oligonucleotide (e.g., 20-24-mer) was shown to provide a similar level of exon skipping as the longer oligonucleotide (e.g., 25-mer) as taught by Platenburg, Wilton, and Harding. As such, there is no scientifically valid reason for a relevant artisan of ordinary skill to predict no exon skipping activity when the prior

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art's 25-mer is truncated from the 3' end to produce 21-mer, 22-mer, and 23-mer oligonucleotides.

Note that “obviousness cannot be avoided simply by a showing of some degree of unpredictability in the art so long as there was a reasonable probability of success.” *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1364 [82 USPQ2d 1321] (Fed. Cir. 2007).

Applicant points out “Exhibit 1”, “Exhibit 2”, “Exhibit 3”, and “Exhibit 4” and argues that nucleotide sequence changes can result in unpredictable effects. In response, it is noted that the references and teachings in Exhibits 1-4 relied on by applicant do not pertain to exon skipping oligonucleotides that differ by 2, 3, or 4 nucleotides only in the 3' end region. No reference relied on by applicant teaches that one should expect abolishment of exon skipping activity when using 3' end-truncated oligonucleotides that differ by 2, 3, or 4 nucleotides only in the 3' end region. Again, the mere possible variability of exon skipping activity does not amount to the level of absolute unpredictability in view of the experimental results shown by Platenburg, Wilton, and Harding and the “obviousness cannot be avoided simply by a showing of some degree of unpredictability in the art so long as there was a reasonable probability of success.”

In addition, it is noted that claims 16, 22, 24, and 26 are merely directed to an “antisense oligomer”. There is no functionality or specific activity level required for the claims, especially in view of the inventor-provided definition of the term “antisense oligomer”, which is defined to “refer to a sequence of cyclic subunits, each bearing a base-pairing moiety, linked by intersubunit linkages that allow the base-pairing moieties to hybridize to a target sequence in a nucleic acid (typically an RNA) by Watson-Crick base pairing, to form a nucleic acid:oligomer heteroduplex within the target sequence.” See page 20.

Now, regarding claims 23, 25, and 27 reciting a “pharmaceutical composition” in the preamble without reciting any specific functionality or activity level, it is noted that the mere

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recitation of “pharmaceutical” in the preamble is interpreted as intended use. Since the prior art's 25-mer PMO was shown to be “active” in inducing exon 44 skipping, and since 3' end-truncated, 2-4-nt shorter exon skipping oligonucleotides were reasonably, if not absolutely, predicted to be also active in inducing exon skipping in view of the teachings of Platenburg, Wilton, and Harding, one of ordinary skill in the art would have reasonably expected that SEQ ID NOs:4-6 would serve the intended pharmaceutical use. Further, even if claims 16, 22, 24, and 26 should be interpreted as oligomers having exon skipping activity, one of ordinary skill in the art would have had a reasonable expectation of success/predictability for a reasonable level of exon skipping with SEQ ID NOs:4-6 truncated from the prior art's 25-mer based on the teachings and actual demonstration of Platenburg, Wilton, and Harding.

Note that for obviousness under §103, “all that is required is a reasonable expectation of success”, and it does not require “absolute predictability of success”. See *In re O'Farrell*, 853 F.2d 894, 7 USPQ2d 1673 (Fed. Cir. 1988) at 1681.

In view of the foregoing, applicant's arguments are not found persuasive.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d

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2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit <http://www.uspto.gov/forms/>. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to <http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp>.

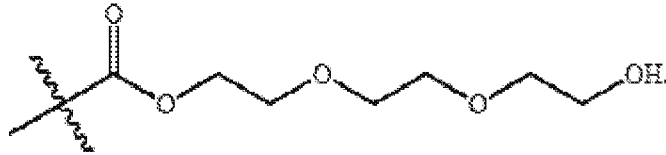
Claims 16 and 21-27 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-32 of U.S. Patent No. 8,779,128 B2 in view of Sazani et al. (WO 2010/048586 A1, of record), Platenburg et al. (US 2012/0059042 A1, applicant's citation), Wilton et al. (US 2008/0200409 A1, applicant's citation), and Harding et al. (*Molecular Therapy*, 2007, 15:157-166, of record).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are an obvious variation of and encompassed by the '128 patent claims drawn to a morpholino oligomer having the 5' terminus structure as claimed in claim 30 shown below:

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30. The oligomer of claim 26, wherein R¹⁹ is piperiziny1 or



Note that the above structure is identical to the 5' terminus structure claimed in the instant claims.

Now, the meaning of the “oligomer” claimed in the ‘128 patent claims reads on SEQ ID NO:22 disclosed in Table 11 of the ‘128 patent as below:

Exon44 -A

GATCTGTCAAATCGCCTGCAGGTAA

22

Note that the above sequence comprises the entire sequence of SEQ ID NOs:4, 5, and 6 claimed in the instant case. As such, the oligomer claimed in the '128 patent claims reads on SEQ ID NO:22 having the 5' terminus structure claimed in claim 30.

It would have been obvious to one of ordinary skill in the art to produce 3' end-truncated oligonucleotides of shorter lengths than SEQ ID NO:22 because it is more economical to synthesize shorter oligonucleotides, and because it was known to synthesize dystrophin exon skipping oligonucleotides of 21, 22, and 23 nucleotides in length as taught by Sazani et al. (see claim 1 and page 41), Platenburg (see a 21-mer SEQ ID NO:8, a 22-mer SEQ ID NO:12, a 23-mer SEQ ID NO:14, and 23-mer “PS 194”), and Wilton (see 21-mer “H8A(-03+18)”), and because 3' end-truncated oligonucleotides of shorter lengths (e.g., 19-mer, 20-mer, 21-mer, and 24-mer) were known to be as effective as longer oligonucleotides (e.g., 25-mer) in inducing dystrophin exon skipping as demonstrated by Platenburg, Wilton, and Harding.

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Applicant's arguments filed on February 18, 2016 have been fully considered but they are not persuasive for the same reasons provided in the §103 rejection above, which is fully incorporated by reference herein thus will not be repeated.

Claims 16 and 21-27 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-3, 15, 17-20, 32, 34, 38, and 43 of copending Application No. 14/942,629 in view of Hanson (US 2012/0289457 A1, of record).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are an obvious variation of and encompassed by the '629 claims drawn to an oligonucleotide of 20-50 or 20-30 bases in length (thus reading on 21-mer, 22-mer, and 23-mer) comprising at least 10 bases of SEQ ID NO:1, which comprises the entire SEQ ID NO:5 and SEQ ID NO:6 claimed in the instant case and which renders obvious SEQ ID NO:4 claimed in the instant case. Further, it would have been obvious to utilize the art-recognized Hanson's exon skipping PMO comprising a delivery conjugate, which is a 5' terminus triethylene glycol ("EG3") linked to the PMO via a piperazine linker, thereby arriving at the instant claims.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANA SHIN whose telephone number is (571)272-8008. The examiner can normally be reached on Monday through Thursday, 7am-5:30pm EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin
Primary Examiner
Art Unit 1674

/DANA SHIN/
Primary Examiner, Art Unit 1674



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/214,480	03/14/2014	Richard K. Bestwick	AVN-013B	3826

123147 7590 10/19/2015
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

EXAMINER

SHIN, DANA H

ART UNIT	PAPER NUMBER
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1674

NOTIFICATION DATE	DELIVERY MODE
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10/19/2015

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipboston.docketing@nelsonmullins.com
chris.schlauch@nelsonmullins.com
ipqualityassuranceboston@nelsonmullins.com

Application No.
14/214,480
#: 58306Applicant(s)
BESTWICK ET AL.**Office Action Summary**Examiner
DANA SHINArt Unit
1674AIA (First Inventor to File)
Status
No**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8-17-2015.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 16 and 22-27 is/are pending in the application.
 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 16 and 22-27 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
 Paper No(s)/Mail Date ____.
- 3) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. ____.
- 4) ☐ Other: ____.

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DETAILED ACTION

The present application is being examined under the pre-AIA first to invent provisions.

Status of Application/Amendment/Claims

This Office action is in response to the communications filed on August 17, 2015.

Currently, claims 16 and 22-27 are pending and under examination on the merits in the instant application.

The following rejections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

Response to Arguments and Amendments

Withdrawn Rejections

Any rejections not repeated in this Office action are hereby withdrawn.

Maintained Rejections

Claim Rejections - 35 USC § 102

Claims 23, 25, and 27 remain rejected under pre-AIA 35 U.S.C. 102(a) and 102(e) as being anticipated by Hanson (US 2012/0289457 A1) for the reasons of record as set forth in the Office action mailed on April 17, 2015 and for the reasons stated below.

Applicant's arguments filed on August 17, 2015 have been fully considered but they are not found persuasive. Applicant argues that the specific chemical structures of A, C, G, and T as newly added in the claims are not taught by Hanson. In response, applicant's attempt "to clarify with a chemical structure the antisense oligomer" is not found persuasive to distinguish over

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Hanson's SEQ ID NO:22 because it is inherent that Hanson's A, C, G, and T have the recited chemical structures, because they are the art-recognized structures of A, C, G, and T. As such, the mere fact that Hanson did not expressly disclose the well-known, art-recognized knowledge regarding the chemical structures of A, C, G, and T bases is not sufficient to overcome this rejection. Accordingly, this rejection is maintained.

Claims 23, 25, and 27 remain rejected under pre-AIA 35 U.S.C. 102(a) and 102(e) as being anticipated by Hanson (US 2012/0065169 A1) for the reasons of record as set forth in the Office action mailed on April 17, 2015 and for the reasons stated below.

Applicant's arguments filed on August 17, 2015 have been fully considered but they are not found persuasive. Applicant argues that the specific chemical structures of A, C, G, and T as newly added in the claims are not taught by Hanson. In response, applicant's attempt "to clarify with a chemical structure the antisense oligomer" is not found persuasive to distinguish over Hanson's SEQ ID NO:22 because it is inherent that Hanson's A, C, G, and T have the recited chemical structures, because they are the art-recognized structures of A, C, G, and T. As such, the mere fact that Hanson did not expressly disclose the well-known, art-recognized knowledge regarding the chemical structures of A, C, G, and T bases is not sufficient to overcome this rejection. Accordingly, this rejection is maintained.

Claim Rejections - 35 USC § 103

Claims 16 and 22-27 remain rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Sazani et al., Hanson (US 2012/0289457 A1), and Harding et al. for the reasons of record as set forth in the Office action mailed on April 17, 2015 and for the reasons stated below.

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Applicant's arguments filed on August 17, 2015 have been fully considered but they are not found persuasive. Applicant argues that no prior art cited teaches the specific chemical structures. In response, the alleged “specific chemical structures” are merely art-recognized, known structures of A, C, G, and T bases with art-recognized, known morpholino linkage structures.

Applicant argues that one skilled in the art would have “no reason or motivation” to make Sazani’s oligonucleotide or Hanson’s oligonucleotide shorter. In response, it is noted that the *KSR* decision forecloses the argument that a specific suggestion or motivation or teaching is required to support a finding of obviousness. See the precedential opinion rendered by the Board of Patent Appeals and Interferences in *Ex parte Smith* (Bd. Pat. App. & Interf. Appeal 2007-1925, June 25, 2007) (citing *KSR*, 127 S.Ct. at 1741, 82 USPQ2d at 1396).

Furthermore, the last Office action clearly and expressly set forth a reason/motivation as to why one skilled in the art would arrive at the instantly claimed shorter oligonucleotides “so as to **more economically synthesize** dystrophin exon 44 skipping oligonucleotides **at a reduced synthesis cost** as compared to the cost of producing a 25-mer oligonucleotide” (emphasis added). See page 8.

The Federal Circuit has recognized that “an implicit motivation to combine exists not only when a suggestion may be gleaned from the prior art as a whole, but when the “improvement” is technology-independent and the combination of references results in a product or process that is more desirable, for example because it is stronger, **cheaper**, cleaner, faster, lighter, smaller, more durable, or more efficient.” (emphasis added). *DyStar Textilfarben GmbH & Co. Deutschland KG v. C. H. Patrick Co.*, 464 F.3d 1356, 1368 (Fed. Cir. 2006).

Applicant asserts that there is “no reasonable expectation of success” because of “a significant level of unpredictability in the efficacy of different antisense oligonucleotides”. In

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response, the alleged unpredictable “efficacy” is irrelevant to the instant product claims, which do not require any “efficacy” or any particular, specific level of exon skipping. Even for claims 23, 25, and 27 that have been amended to recite “pharmaceutical composition” do not require any “efficacy”, because the preamble language is a mere intended use language in a product claim thus does not serve as a claim limitation. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). As such, applicant's arguments are irrelevant to the instantly claimed subject matter.

In addition, applicant did not provide any persuasive, convincing arguments supporting her alleged complete lack of reasonable expectation of success in making shorter oligonucleotides than the prior arts' oligonucleotide. As noted in the last Office action, it was routine and conventional to synthesize exon skipping oligonucleotides shorter than 25 nucleotides in length as taught by Sazani et al. and Harding et al. thus making exon skipping oligonucleotides of 21-23 nucleotides in length was fully within the technical grasp of one of ordinary skill in the art. Furthermore, truncating the 3' end region sequence of a longer exon skipping oligonucleotide was a known methodology of synthesizing shorter exon skipping oligonucleotides as taught by Harding et al., who reported that 20-mer and 25-mer “induced similar levels” of exon skipping when the 20-mer is the product that is truncated at the 3' end region of the 25-mer. Thus, there would not have been the alleged complete lack of reasonable expectation of synthesizing 21-23-mer oligonucleotides by truncating the 3' end region of Sazani's 25-mer oligonucleotide. Note that for obviousness under §103, “all that is required is a reasonable expectation of success”, and it does not require “absolute predictability of success”. See *In re O 'Farrell*, 853 F.2d 894, 7 USPQ2d 1673 (Fed. Cir. 1988) at 1681. In addition, note that “obviousness cannot be avoided simply by a showing of some degree of unpredictability in

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the art so long as there was a reasonable probability of success.” *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1364 [82 USPQ2d 1321] (Fed. Cir. 2007).

Applicant argues that one skilled in the art has no motivation to combine the cited references because Harding et al. reported that the 25-mer, longer oligonucleotide is the “preferred compound” and is “more effective” than shorter oligonucleotides. Again, applicant’s attention is directed to the fact that the instant product claims do not require any “efficacy”. Furthermore, the motivation to make shorter, “cheaper” oligonucleotides was clearly set forth in the last Office action and supported by *DyStar Textilfarben GmbH & Co. Deutschland KG v. C. H. Patrick Co.*, 464 F.3d 1356, 1368 (Fed. Cir. 2006).

Moreover, applicant did not provide any persuasive counterevidence such that truncating only 1, 2, or 3 nucleotides from the 3' end of Sazani's SEQ ID NO:4 would completely destroy exon skipping function, despite the objective evidence that truncation of 5 nucleotides from the 3' end “induced similar levels” of exon skipping as the longer oligonucleotide as reported by Harding et al. It may be possible that the truncation of 1-3 nucleotides may not induce same level of exon skipping as Sazani's SEQ ID NO:4. However, such possibility does not provide any evidence that the truncated, shorter oligonucleotides would be useless as exon skipping oligonucleotides thus would teach one skilled in the art away from making them despite the lower, cheaper synthesis costs associated with the shorter oligonucleotide synthesis.

In response to applicant’s argument regarding the 25-mer being “preferred” over shorter oligonucleotides, it is noted that an obvious product that is described less desirable does not become patentable.

“A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use.” *In re Gurley* (27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994).

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Further, a careful reading of the passage pointed out in Harding by applicant reveals that the 25-mer was suggested as a preferred compound because “it is **effective at lower concentrations** and shows **extended duration** of induced exon skipping.” (emphasis added). As such, the conditions for the 25-mer being the preferred compound over a 20-mer are not claimed features. The instant claims are mere product claims that do not require any particular exon skipping efficacy, concentrations, or longevity. Further, the objective fact is that Harding et al. did not whatsoever teach that a 20-mer should be avoided or is not effective. Harding et al. clearly provided options for making shorter exon skipping oligonucleotides by truncating the 3’ end of a longer oligonucleotide and expressly reported that the 20-mer and 25-mer “induced similar levels” or exon skipping at 200 nM or higher.

In view of the foregoing, this rejection is maintained.

Double Patenting

Claims 16 and 22-27 remain rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-32 of U.S. Patent No. 8,779,128 B2 in view of Sazani et al. and Harding et al. for the reasons of record as set forth in the Office action mailed on April 17, 2015 and for the reasons stated below.

Applicant's arguments filed on August 17, 2015 have been fully considered but they are not found persuasive. Applicant argues that one skilled in the art does not have a motivation and a reasonable expectation of success as explained in the §103 rejection. In response, applicant's arguments are not found persuasive for the same reasons provided above in the §103 rejection, which is fully incorporated by reference herein thus will not be repeated.

In view of the foregoing, this rejection is maintained.

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Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANA SHIN whose telephone number is (571)272-8008. The examiner can normally be reached on Monday through Thursday, 7am-5:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin
Primary Examiner
Art Unit 1674

/DANA SHIN/
Primary Examiner, Art Unit 1674

Application No.: 14/214,480 (Information Disclosure Statement)

Docket No.: AVN-013B

Office Actions (copies enclosed)			
Examiner's Initials	Serial No.	Date Mailed from USPTO	Examiner
	13/826,880	June 22, 2015	Kimberly Chong
	14/223,634	April 15, 2015	Kimberly Chong
	14/317,952	March 18, 2015	Kimberly Chong
	14/214,567	June 24, 2015	E. Poliakova-Georgan
	14/213,607	April 1, 2015	D.H. Shin
	14/108,137	April 29, 2015	T.A. Vivlemore
	14/213,641	March 31, 2015	D.H. Shin

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /DS/

Applicants respectfully request that the Examiner initial the blank column next to the cited Office Action, to indicate that the information has been considered by the Examiner. Alternatively, Applicants request that the Examiner insert the phrase, "All references considered except where lined through," on each page of the Information Disclosure Statement, along with the Examiner's initials.

/Dana Shin/ 10/14/2015

The Examiner is requested to review the file histories of these applications, including cited references, Office Actions, Responses, etc., and is asked to contact Applicant's Attorney if the Examiner would like the Applicant to supply copies of any or all of the information included in any of these applications. For any of these applications, if Applicant's Attorney is not contacted by the Examiner with such a request, then it will be concluded that the Examiner has reviewed or will review the file content of these applications.

This statement is not to be interpreted as a representation that the cited documents are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any documents herein be construed *per se* as a representation that such document is prior art. Moreover, Applicants understand the Examiner will make an independent evaluation of the cited documents.

It is submitted that the Information Disclosure Statement is in compliance with 37 C.F.R. § 1.98 and the Examiner is respectfully requested to consider the listed references.

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Filed

Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		14214480	
	Filing Date		2014-03-14	
	First Named Inventor		Richard K. BESTWICK	
	Art Unit		1674	
	Examiner Name		D. H. Shin	
	Attorney Docket Number		AVN-013B	

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	14214480
Filing Date	2014-03-14
First Named Inventor	Richard K. BESTWICK
Art Unit	1674
Examiner Name	D. H. Shin
Attorney Docket Number	AVN-013B

1	University of Western Australia v. Academisch Ziekenhuis Leiden, Clean Copy of Claims and Sequences, 5 pages, dated October 15, 2014, Interference No. 106,013, (Exhibit Number 2050 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
2	University of Western Australia v. Academisch Ziekenhuis Leiden, Decision- Motions- 37 CFR§ 41.125(a), filed in Patent Interference No. 106,013, June 22, 2015, pages 1-12 (Doc 192).	<input type="checkbox"/>
3	University of Western Australia v. Academisch Ziekenhuis Leiden, Declaration of Erik Sontheimer dated November 17, 2014, Exhibit 1012 filed in Patent Interference Nos. 106,007 and 106,008, 112 pages, filed November 18, 2014	<input type="checkbox"/>
4	University of Western Australia v. Academisch Ziekenhuis Leiden, Declaration of Interference, Patent Interference No. 106,007, 7 pages, dated July 18, 2014 (Doc 1)	<input type="checkbox"/>
5	University of Western Australia v. Academisch Ziekenhuis Leiden, Declaration of Interference, Patent Interference No. 106,008, 7 pages, dated July 24, 2014 (Doc 1)	<input type="checkbox"/>
6	University of Western Australia v. Academisch Ziekenhuis Leiden, Declaration of Interference, Patent Interference No. 106,013, 8 pages, dated September 29, 2014 (Doc 1)	<input type="checkbox"/>
7	University of Western Australia v. Academisch Ziekenhuis Leiden, Declaration of Matthew J.A. Wood, Patent Interference Nos. 106,007, 106,008 and 106,013, 184 pages, dated November 18, 2014 (Exhibit Number 2081 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
8	University of Western Australia v. Academisch Ziekenhuis Leiden, Joint Stipulation regarding Time Periods 2, 3 and 4, 3 pages, Patent Interference No. 106,013, (Doc 135), dated November 25, 2015.	<input type="checkbox"/>
9	University of Western Australia v. Academisch Ziekenhuis Leiden, Joint Stipulation regarding Time Periods 3-4, 4 pages, Patent Interference No. 106,007, (Doc 243), dated January 29, 2015.	<input type="checkbox"/>
10	University of Western Australia v. Academisch Ziekenhuis Leiden, Joint Stipulation regarding Time Periods 3-4, 4 pages, Patent Interference No. 106,008, (Doc 247), dated January 29, 2015.	<input type="checkbox"/>
11	University of Western Australia v. Academisch Ziekenhuis Leiden, Joint Stipulation regarding Time Periods 3-4, 4 pages, Patent Interference No. 106,013, (Doc 137), dated January 29, 2015.	<input type="checkbox"/>

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12	University of Western Australia v. Academisch Ziekenhuis Leiden, Joint Stipulation Regarding Time Periods 4-6, 4 pages, Patent Interference No. 106,007, dated March 19, 2015 (Doc 416)	<input type="checkbox"/>
13	University of Western Australia v. Academisch Ziekenhuis Leiden, Joint Stipulation Regarding Time Periods 4-6, 4 pages, Patent Interference No. 106013, (Doc 151), dated March 19, 2015.	<input type="checkbox"/>
14	University of Western Australia v. Academisch Ziekenhuis Leiden, Joint Stipulation Regarding Time Periods 4-6, 4 pages, Patent Interference No.106,008, (Doc 424), dated March 19, 2015.	<input type="checkbox"/>
15	University of Western Australia v. Academisch Ziekenhuis Leiden, Miscellaneous Order under 37 CFR 41.104(a), 4 pages, Patent Interference Nos. 106,007 and 106,008, dated December 15, 2014	<input type="checkbox"/>
16	University of Western Australia v. Academisch Ziekenhuis Leiden, Order - Authorizing Motions, Patent Interference No. 106,007, 3 pages, dated September 26, 2014 (Doc 20)	<input type="checkbox"/>
17	University of Western Australia v. Academisch Ziekenhuis Leiden, Order - Authorizing Motions, Patent Interference No. 106,007, 6 pages, dated September 23, 2014 (Doc 19)	<input type="checkbox"/>
18	University of Western Australia v. Academisch Ziekenhuis Leiden, Order - Authorizing Motions, Patent Interference No. 106,008, 6 pages, dated September 23, 2014 (Doc 18)	<input type="checkbox"/>
19	University of Western Australia v. Academisch Ziekenhuis Leiden, Order - Miscellaneous 37 C.F.R. 41.104(a), 2 pages, Patent Interference Nos. 106,007, 106,008, 106,013, dated November 14, 2014	<input type="checkbox"/>
20	University of Western Australia v. Academisch Ziekenhuis Leiden, Order to Show Cause- 37 CFR§ 41.104(a), filed in Patent Interference No. 106,013, June 22, 2015, pages 1-3 (Doc 193).	<input type="checkbox"/>
21	University of Western Australia v. Academisch Ziekenhuis Leiden, Redecoration, Patent Interference No. 106,008, 2 pages, dated September 23, 2014 (Doc 19)	<input type="checkbox"/>
22	University of Western Australia v. Academisch Ziekenhuis Leiden, Second Declaration of Matthew J. A. Wood, M.D., D. PHIL., Patent Interference Nos. 106,007 and 106,008, 78 pages, dated February 17, 2015 (Exhibit Number 2116 filed in interferences 106,007 and 106,008, on February 17, 2015.	<input type="checkbox"/>

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23	University of Western Australia v. Academisch Ziekenhuis Leiden, Statement Concerning Initial Settlement Discussions, 3 pages, Patent Interference No. 106,013, (Doc 136), dated December 30, 2014.	<input type="checkbox"/>
24	University of Western Australia v. Academisch Ziekenhuis Leiden, Statement Concerning Subsequent Settlement Discussions, 3 pages, Patent Interference No. 106,007, (Doc 242), dated December 30, 2014.	<input type="checkbox"/>
25	University of Western Australia v. Academisch Ziekenhuis Leiden, Statement Concerning Subsequent Settlement Discussions, 3 pages, Patent Interference No. 106,008, (Doc 246), dated December 30, 2014.	<input type="checkbox"/>
26	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Response to Order to Show Cause, filed in Patent Interference No. 106,013, July 20, 2015, pages 1-28 (Doc 194).	<input type="checkbox"/>
27	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Exhibit List as of April 10, 2015, filed in Patent Interference No. 106,007, April 10, 2015, pages 1-10 (Doc 456).	<input type="checkbox"/>
28	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Exhibit List as of April 10, 2015, filed in Patent Interference No. 106,008, April 10, 2015, pages 1-10 (Doc 464).	<input type="checkbox"/>
29	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Exhibit List as of April 3, 2015, filed in Interference 106007, April 3, 2015, pages 1-10 (Doc 431).	<input type="checkbox"/>
30	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Exhibit List as of April 3, 2015, filed in Interference 106008, April 3, 2015, pages 1-10 (Doc 439).	<input type="checkbox"/>
31	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Exhibit List as of April 3, 2015, filed in Interference 106013, April 3, 2015, pages 1-10 (Doc 153).	<input type="checkbox"/>
32	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Miscellaneous Motion 4 (to exclude evidence), filed in Patent Interference No. 106,007, April 10, 2015, pages 1-21 (Doc 455).	<input type="checkbox"/>
33	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Miscellaneous Motion 4 (to exclude evidence), filed in Patent Interference No. 106,008, April 10, 2015, pages 1-21 (Doc 463).	<input type="checkbox"/>

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34	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Opposition 1 (Regarding Patentability Under 35 U.S.C. § 102/103), 38 pages, Patent Interference No. 106,007, (Doc 393), dated February 17, 2015	<input type="checkbox"/>
35	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Opposition 1 (Regarding Patentability Under 35 U.S.C. § 102/103), 39 pages, Patent Interference No. 106,008, (Doc 402), dated February 17, 2015	<input type="checkbox"/>
36	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Opposition 2 (To Retain UWA's Benefit of AU 2004903474), 31 pages, Patent Interference No. 106,008, (Doc 403), dated February 17, 2015	<input type="checkbox"/>
37	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Opposition 2 (To Retain UWA's Benefit of AU 2004903474), 37 pages, Patent Interference No. 106,007, (Doc 394), dated February 17, 2015	<input type="checkbox"/>
38	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Opposition 3 (Regarding Patentability Under 35 U.S.C. § 101), 22 pages, Patent Interference No. 106,007, (Doc 395), dated February 17, 2015	<input type="checkbox"/>
39	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Opposition 3 (Regarding Patentability Under 35 U.S.C. § 101), 22 pages, Patent Interference No. 106,008, (Doc 404), dated February 17, 2015	<input type="checkbox"/>
40	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Opposition 4 (To deny entry of AZL's Proposed New Claims 104 and 105), 36 pages, Patent Interference No. 106,007, (Doc 397), dated February 17, 2015	<input type="checkbox"/>
41	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Opposition 4 (To deny entry of AZL's Proposed New Claims 30 and 31), 36 pages, Patent Interference No. 106,008, (Doc 405), dated February 17, 2015	<input type="checkbox"/>
42	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Reply 1 (to AZL Opposition 1), filed April 3, 2015 in Interference 106007, pages 1-28 (Doc 428).	<input type="checkbox"/>
43	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Reply 1 (to AZL Opposition 1), filed April 3, 2015 in Interference 106008, pages 1-28, (Doc 436).	<input type="checkbox"/>
44	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Reply 1 (to Maintain the Interference) filed April 3, 2015 in Interference 106013, pages 1-17 (Doc 152).	<input type="checkbox"/>

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Examiner Name	D. H. Shin
Attorney Docket Number	AVN-013B

45	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Reply 2 (to AZL Opposition 2) filed April 3, 2015 in Interference 106007, pages 1-22 (Doc 429)	<input type="checkbox"/>
46	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Reply 2 (to AZL Opposition 2) filed April 3, 2015 in Interference 106008, pages 1-22 (Doc 437).	<input type="checkbox"/>
47	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Reply 3 (for Judgment under 35 U.S.C. §135(b)) filed April 3, 2015 in Interference 106008, pages 1-19 (Doc 438).	<input type="checkbox"/>
48	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Reply 3 (to Institute an Interference) filed April 3, 2015 in Interference 106007, pages 1-17 (Doc 430).	<input type="checkbox"/>
49	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Reply 4 (To Exclude Evidence), filed in Patent Interference No. 106,007, May 12, 2015, pages 1-13 (Doc 467).	<input type="checkbox"/>
50	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Reply 4 (To Exclude Evidence), filed in Patent Interference No. 106,008, May 12, 2015, pages 1-13 (Doc 475).	<input type="checkbox"/>

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		14214480	
	Filing Date		2014-03-14	
	First Named Inventor	Richard K. BESTWICK		
	Art Unit	1674		
	Examiner Name	D. H. Shin		
	Attorney Docket Number	AVN-013B		

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Application Number
30323

14214480

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Filing Date

2014-03-14

First Named Inventor

Richard K. BESTWICK

Art Unit

1674

Examiner Name

D. H. Shin

Attorney Docket Number

AVN-013B

1	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Request for Oral Argument, filed in Patent Interference No. 106,007, April 10, 2015, pages 1-4 (Doc 457).	<input type="checkbox"/>
2	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Request for Oral Argument, filed in Patent Interference No. 106,008, April 10, 2015, pages 1-4 (Doc 465).	<input type="checkbox"/>
3	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Request for Oral Argument, filed in Patent Interference No. 106,013, April 10, 2015, pages 1-3 (Doc 190).	<input type="checkbox"/>
4	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Revised Designation of Lead and Backup Counsel, 4 pages, Patent Interference No. 106,007, (Doc 415), dated March 10, 2015.	<input type="checkbox"/>
5	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Revised Designation of Lead and Backup Counsel, 4 pages, Patent Interference No. 106,013, (Doc 150), dated March 10, 2015.	<input type="checkbox"/>
6	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia Revised Designation of Lead and Backup Counsel, 5 pages, Patent Interference No. 106,008, (Doc 423), dated March 10, 2015.	<input type="checkbox"/>
7	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia, Exhibit List as of February 17, 2015, 8 pages, Patent Interference No. 106,007, (Doc No. 398) dated February 17, 2015.	<input type="checkbox"/>
8	University of Western Australia v. Academisch Ziekenhuis Leiden, University of Western Australia, Exhibit List as of February 17, 2015, 8 pages, Patent Interference No. 106,008, (Doc No. 406) dated February 17, 2015.	<input type="checkbox"/>
9	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Clean Copy of Involved Claims and Sequence, Patent Interference No. 106,007, 8 pages, dated August 1, 2014 (Doc 12)	<input type="checkbox"/>
10	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Clean Copy of Involved Claims and Sequence, Patent Interference No. 106,008, 8 pages, dated August 7, 2014 (Doc 12)	<input type="checkbox"/>
11	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Clean Copy of Involved Claims and Sequence, Patent Interference No. 106,013, 7 pages, dated October 14, 2014 (Doc 7)	<input type="checkbox"/>

**INFORMATION DISCLOSURE
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Application Number	14214480
Filing Date	2014-03-14
First Named Inventor	Richard K. BESTWICK
Art Unit	1674
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Attorney Docket Number	AVN-013B

12	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Exhibit List as of November 18, 2014, 7 pages, Patent Interference No. 106,008, dated November 18, 2014 (Doc 216)	<input type="checkbox"/>
13	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Exhibit list, 7 pages, Patent Interference No. 106,007, dated November 18, 2014 (Doc 213)	<input type="checkbox"/>
14	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Exhibit list, 7 pages, Patent Interference No. 106,013, dated November 18, 2014 (Doc 134)	<input type="checkbox"/>
15	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Exhibit List, 7 pages, Patent Interference Nos. 106,008, dated December 12, 2014 (Doc 221)	<input type="checkbox"/>
16	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Exhibit List, 8 pages, Patent Interference No. 106,007, dated December 12, 2014 (Doc 217)	<input type="checkbox"/>
17	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA List of Proposed Motions, Patent Interference No. 106,007, 7 pages, dated September 10, 2014 (Doc 17)	<input type="checkbox"/>
18	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA List of Proposed Motions, Patent Interference No. 106,008, 6 pages, dated September 10, 2014 (Doc 16)	<input type="checkbox"/>
19	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Miscellaneous Motion 1 (for authorization to file a Terminal Disclaimer), 5 pages, Patent Interference No. 106,008, dated October 17, 2014 (Doc 22)	<input type="checkbox"/>
20	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Motion 1 (For Judgment Under 35 U.S.C., section 112(a)), 40 pages, Patent Interference No. 106,007, dated November 18, 2014 (Doc 210)	<input type="checkbox"/>
21	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Motion 1 (For Judgment Under 35 § 112(a)) Patent Interference No. 106,008 (Doc 213), Pages 38, on November 18, 2014	<input type="checkbox"/>
22	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Motion 1 (To Maintain Interference between UWA US Patent No. 8,486,907 and AZL USSN 14/198,992), 45 pages, Patent Interference No. 106,013, dated November 18, 2014 (Doc 133)	<input type="checkbox"/>

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Application Number	14214480
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Art Unit	1674
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23	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Motion 2 (For Judgment Under 35 U.S.C. section 112(b)), 32 pages, Patent Interference No. 106,008, dated November 18, 2014 (Doc 214)	<input type="checkbox"/>
24	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Motion 2 (For Judgment Under 35 U.S.C. section 112(b)), 34 pages, Patent Interference No. 106,007, dated November 18, 2014 (Doc 211)	<input type="checkbox"/>
25	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Motion 3 (For judgment that Claims 11-12, 14-15, and 17-29 of Application No. 13/550,210 are barred under 35 U.S.C. section 135(b)), 25 Pages, Patent Interference No. 106,008, dated November 18, 2014 (Doc 215)	<input type="checkbox"/>
26	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Motion 3 (requesting an additional Interference between UWA U.S. Patent No. 8,455,636 and AZL USSN 14/248,279), 36 pages, Patent Interference No. 106,007, dated November 18, 2014 (Doc 212)	<input type="checkbox"/>
27	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Filing Priority Statement, 2 pages, Patent Interference No. 106,007, dated November 18, 2014 (Doc 215)	<input type="checkbox"/>
28	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Filing Priority Statement, 2 pages, Patent Interference No. 106,008, dated November 18, 2014 (Doc 218)	<input type="checkbox"/>
29	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Recent Authority, filed in Patent Interference No. 106,007, July 2, 2015, pages 1-16 (Doc 469).	<input type="checkbox"/>
30	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Recent Authority, filed in Patent Interference No. 106,008, July 2, 2015, pages 1-16, (Doc 477).	<input type="checkbox"/>
31	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Related Proceedings, Patent Interference No. 106,007, 3 pages, dated August 1, 2014 (Doc 11)	<input type="checkbox"/>
32	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Related Proceedings, Patent Interference No. 106,008, 5 pages, dated August 7, 2014 (Doc 11)	<input type="checkbox"/>
33	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Related Proceedings, Patent Interference No. 106,013, 3 pages, dated October 14, 2014 (Doc 6)	<input type="checkbox"/>

Application Number
30326

14214480

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Filing Date

2014-03-14

First Named Inventor

Richard K. BESTWICK

Art Unit

1674

Examiner Name

D. H. Shin

Attorney Docket Number

AVN-013B

34	US 7,960,541 (Wilton et al.), Pages 84, Exhibit Number 1002 filed in interferences 106,007 and 106,008 on November 18, 2014.	<input type="checkbox"/>
35	US 8,450,474 (Wilton et al.), Pages 95, Exhibit Number 1087 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
36	US 8,455,634 (Wilton et al.) Pages 96, Exhibit Number 1088 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
37	US 8,455,635 (Wilton et al.), Pages 96, Exhibit Number 1089 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
38	US 8,455,636 (Wilton et al.), Pages 92, Exhibit Number 1003 filed in interferences 106,007 and 106,008 on November 18, 2014.	<input type="checkbox"/>
39	US 8,476,423 (Wilton et al.), Pages 95, Exhibit Number 1111 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
40	US 8,501,703 (Bennett et al.), Pages 16, Exhibit Number 1090 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
41	US 8,501,704 (Mourich et al.), Pages 39, Exhibit Number 1091 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
42	US 8,524,676 (Stein et al.), Pages 28, Exhibit Number 1092 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
43	US 8,524,880 (Wilton et al.), Pages 89, Exhibit Number 1093 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
44	US 8,536,147 (Weller et al.), Pages 95, Exhibit Number 1094 filed in interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>

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Attorney Docket Number	AVN-013B	

45	US 8,592,386 (Mourich et al.), Pages 46, Exhibit Number 1095 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
46	US 8,618,270 (Iversen et al.), Pages 28, Exhibit Number 1096 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
47	US 8,637,483 (Wilton et al.), Pages 157, Exhibit Number 1097 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
48	US 8,697,858 (Iversen), Pages 95, Exhibit Number 1098 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
49	US 8,703,735 (Iversen et al.) Pages 73, Exhibit Number 1099 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
50	US 8,741,863 (Moulton et al.), Pages 68, Exhibit Number 1100 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>

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	Filing Date		2014-03-14	
	First Named Inventor	Richard K. BESTWICK		
	Art Unit	1674		
	Examiner Name	D. H. Shin		
	Attorney Docket Number	AVN-013B		

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1	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Opposition 2 (Indefiniteness), 32 pages, Patent Interference No. 106,008, (Doc 401), dated February 17, 2015	<input type="checkbox"/>
2	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Opposition 3 (35 U.S.C. §135(b)), 44 pages, Patent Interference No. 106,008, (Doc 397), dated February 17, 2015	<input type="checkbox"/>
3	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Opposition 3 (Standing Order § 203.1 and 37 C.F.R. § 41.202(a) and (e)), 20 pages, Patent Interference No. 106,007, (Doc 389), dated February 17, 2015.	<input type="checkbox"/>
4	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 1 (For Judgment that UWA's Claims are Unpatentable Under 35 U.S.C. §§ 102 and 103), dated April 3, 2015, filed in Patent Interference No. 106008, pages 1-17 (Doc 431).	<input type="checkbox"/>
5	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 1 (For Judgment that UWA's Claims are Unpatentable Under 35 U.S.C. §§ 102 and 103), dated April 3, 2015, filed in Patent Interference No. 106007, pages 1-17 (Doc 424).	<input type="checkbox"/>
6	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 2 (To Deny the Benefit of AU 2004903474), dated April 3, 2015, filed in Patent Interference No. 106007, pages 1-11(Doc 425).	<input type="checkbox"/>
7	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 2 (To Deny the Benefit of AU 2004903474), dated April 3, 2015, filed in Patent Interference No. 106008, pages 1-12 (Doc 432).	<input type="checkbox"/>
8	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 3 (For Judgment of Unpatentability based on Myriad) dated April 3, 2015, filed in Patent Interference No. 106007, pages 1-12 (Doc 426).	<input type="checkbox"/>
9	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 3 (For Judgment of Unpatentability based on Myriad) dated April 3, 2015, filed in Patent Interference No. 106008, pages 1-13 (Doc 433).	<input type="checkbox"/>
10	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 4 (In Support of Responsive Motion 4 to Add Two New Claims) dated April 3, 2015, filed in Patent Interference No. 106007, pages 1-17 (Doc 427).	<input type="checkbox"/>
11	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Reply 4 (In Support of Responsive Motion 4 to Add Two New Claims) dated April 3, 2015, filed in Patent Interference No. 106008, pages 1-17 (Doc 434).	<input type="checkbox"/>

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12	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Request For Oral Argument, filed in Patent Interference No. 106,007, April 10, 2015, pages 1-3 (Doc 454).	<input type="checkbox"/>
13	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Request For Oral Argument, filed in Patent Interference No. 106,008, April 10, 2015, pages 1-3 (Doc 462).	<input type="checkbox"/>
14	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Responsive Motion 4 (To Add Two New Claims), 57 pages, Patent Interference No. 106,008, (Doc 245), dated December 23, 2014.	<input type="checkbox"/>
15	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Responsive Motion 4 (To Add Two New Claims), 65 pages, Patent Interference No. 106,007, (Doc 241), dated December 23, 2014.	<input type="checkbox"/>
16	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Statement Regarding Oral Argument, filed in Patent Interference No. 106,013, April 10, 2015, pages 1-3 (Doc 189).	<input type="checkbox"/>
17	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden's List of Exhibits as of May 5, 2015, filed in Patent Interference No. 106,007, May 5, 2015, pages 1-18 (Doc 466).	<input type="checkbox"/>
18	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden's List of Exhibits as of May 5, 2015, filed in Patent Interference No. 106,008, May 5, 2015, pages 1-18 (Doc 474).	<input type="checkbox"/>
19	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden's Opposition 4 (To Not Exclude Evidence), filed in Patent Interference No. 106,007, May 5, 2015, pages 1-22 (Doc 465).	<input type="checkbox"/>
20	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden's Opposition 4 (To Not Exclude Evidence), filed in Patent Interference No. 106,008, May 5, 2015, pages 1-21 (Doc 473).	<input type="checkbox"/>
21	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden's Second Supplemental Notice of Real Party in Interest, filed in Patent Interference No. 106,007, May 28, 2015, pages 1-3, (Doc 468)	<input type="checkbox"/>
22	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden's Second Supplemental Notice of Real Party in Interest, filed in Patent Interference No. 106,008, May 28, 2015, pages 1-3, (Doc 476)	<input type="checkbox"/>

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23	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden's Second Supplemental Notice of Real Party in Interest, filed in Patent Interference No. 106,013, May 28, 2015, pages 1-3, (Doc 191)	<input type="checkbox"/>
24	University of Western Australia v. Academisch Ziekenhuis Leiden, ACADEMISH ZIEKENHUIS LEIDEN SUPPLEMENTAL NOTICE OF REAL PARTY IN INTEREST, Pages 3, DOC 149, Patent Interference No. 106,013 dated February 23, 2015.	<input type="checkbox"/>
25	University of Western Australia v. Academisch Ziekenhuis Leiden, ACADEMISH ZIEKENHUIS LEIDEN SUPPLEMENTAL NOTICE OF REAL PARTY IN INTEREST, Pages 3, Doc 413, Patent Interference No. 106,007 dated February 23, 2015.	<input type="checkbox"/>
26		<input type="checkbox"/>
27	University of Western Australia v. Academisch Ziekenhuis Leiden, ACADEMISH ZIEKENHUIS LEIDEN SUPPLEMENTAL NOTICE OF REAL PARTY IN INTEREST, Pages 3, Doc 421, Patent Interference No. 106,008 dated February 23, 2015.	<input type="checkbox"/>
28	University of Western Australia v. Academisch Ziekenhuis Leiden, Amendment and Response, US Application No. 11/233,495, Filed 1/22/2014, 8 pages, (Exhibit Number 2117 filed in interferences 106,007 and 106, 008, on February 17, 2015.	<input type="checkbox"/>
29	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Annotated Copy of Claims, Patent Interference No. 106,007, 15 pages, dated August 15, 2014 (Doc 15)	<input type="checkbox"/>
30	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Annotated Copy of Claims, Patent Interference No. 106,008, 14 pages, dated August 21, 2014 (Doc 14)	<input type="checkbox"/>
31	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Annotated Copy of Claims, Patent Interference No. 106,013, 14 pages, dated October 27, 2014 (Doc 16)	<input type="checkbox"/>
32	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Clean Copy of Claims and Sequences, filed in Patent Interference No. 106,013, 5 pages, dated October 15, 2014 (Doc 12)	<input type="checkbox"/>
33	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Corrected Notice of Related Proceedings, Patent Interference No. 106,007, 3 pages, dated August 1, 2014 (Doc 13)	<input type="checkbox"/>

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34	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Exhibit List, 10 pages, Patent Interference No. 106,007 dated December 23, 2014 (Doc 240)	<input type="checkbox"/>
35	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Exhibit List, 10 pages, Patent Interference No. 106,008, dated December 23, 2014 (Doc 244)	<input type="checkbox"/>
36	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL List of Exhibits, 9 pages, Patent Interference No. 106,007, dated November 18, 2014 (Doc 209)	<input type="checkbox"/>
37	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL List of Exhibits, as of November 18, 2014, 9 pages, Patent Interference No. 106,008, dated November 18, 2014 (Doc 212)	<input type="checkbox"/>
38	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL List of Proposed Motions, Patent Interference No. 106,007, 6 pages, dated September 10, 2014 (Doc 16)	<input type="checkbox"/>
39	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL List of Proposed Motions, Patent Interference No. 106,008, 8 pages, dated September 10, 2014 (Doc 15)	<input type="checkbox"/>
40	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Motion 1 (For Judgment that UWA's Claims are Unpatentable Under 35 U.S.C. sections 102 and 103), 69 pages, Patent Interference No. 106,008, dated November 18, 2014 (Doc 184)	<input type="checkbox"/>
41	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Motion 1 (For Judgment that UWA's Claims are Unpatentable Under 35 U.S.C. §102 and 103), 69 pages, Patent Interference No. 106,007, dated November 18, 2014 (Doc 181)	<input type="checkbox"/>
42	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Motion 2 (To Deny UWA the Benefit of AU 2004903474), 23 pages, Patent Interference No. 106,007, dated November 18, 2014 (Doc 26)	<input type="checkbox"/>
43	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Motion 2 (To Deny UWA the Benefit of AU 2004903474), 24 pages, Patent Interference No. 106,008, dated November 18, 2014 (Doc 29)	<input type="checkbox"/>
44	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Motion 3 (For Judgment of Unpatentability based on Myriad) 20 pages, Patent Interference No. 106,008, dated November 18, 2014 (Doc 30)	<input type="checkbox"/>

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45	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Motion 3 (For Judgment of Unpatentability based on Myriad), 19 pages, Patent Interference No. 106,007, dated November 18, 2014 (Doc 27)	<input type="checkbox"/>
46	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Notice of Related Proceedings, Patent Interference No. 106,007, 3 pages, dated July 31, 2014 (Doc 6)	<input type="checkbox"/>
47	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Notice of Related Proceedings, Patent Interference No. 106,008, 3 pages, dated August 5, 2014 (Doc 7)	<input type="checkbox"/>
48	University of Western Australia v. Academisch Ziekenhuis Leiden, AZL Notice of Related Proceedings, Patent Interference No. 106,013, 3 pages, dated October 15, 2014 (Doc 11)	<input type="checkbox"/>
49	University of Western Australia v. Academisch Ziekenhuis Leiden, Clean Copy of Claims and Sequences, 5 pages, dated August 5, 2014, Interference No. 106,008, (Exhibit Number 2047 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
50	University of Western Australia v. Academisch Ziekenhuis Leiden, Clean Copy of Claims and Sequences, 5 pages, dated July 31, 2014, Interference No. 106,007, (Exhibit Number 2045 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>

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1	SONTHEIMER, Erik J. et al., "The U5 and U6 Small Nuclear RNAs as Active Site Components of the Spliceosome," Science, Vol. 262:1989-1997 (1993) (Exhibit Number 1058 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
2	Standard Operating Procedure FPLC Desalting, Pages 6, Exhibit Number 1144 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
3	Stanton, Robert et al., "Chemical Modification Study of Antisense Gapmers", Nucleic Acid Therapeutics, Vol. 22(5): 344-359 (2012)	<input type="checkbox"/>
4	Statement On A Nonproprietary Name Adopted By the USAN Council, ETEPLIRSEN, Chemical Structure, 2010, page 1-43 or pages 1-5.	<input type="checkbox"/>
5	STEIN, CA, "Delivery of antisense oligonucleotides to cells: a consideration of some of the barriers," Monographic supplement series: Oligos & Peptides - Chimica Oggi - Chemistry Today, Vol. 32(2):4-7 (2014) (Exhibit Number 2022 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
6	STEIN, Cy A. et al., "Therapeutic Oligonucleotides: The Road Not Taken," Clin. Cancer Res., Vol. 17(20):6369-6372 (2011) (Exhibit Number 2026 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
7	STEIN, David et al., "A Specificity Comparison of Four Antisense Types: Morpholino, 2'-O-Methyl RNA, DNA, and Phosphorothioate DNA," Antisense & Nucleic Acid Drug Development, Vol. 7:151-157 (1997)	<input type="checkbox"/>
8	Strober JB, "Therapeutics in Duchenne muscular dystrophy," NeuroRX 2006; 3:225-34.	<input type="checkbox"/>
9	Summary of Professional Experience (Dr. Erik J. Sontheimer), Pages 4, Exhibit Number 1223 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
10	SUMMERTON, James et al., "Morpholino and Phosphorothioate Antisense Oligomers Compared in Cell-Free and In-Cell Systems," Antisense & Nucleic Acid Drug Development, Vol. 7:63-70 (1997)	<input type="checkbox"/>
11	SUMMERTON, James et al., "Morpholino Antisense Oligomers: Design, Preparation, and Properties," Antisense & Nucleic Acid Drug Development, Vol. 7:187-195 (1997)	<input type="checkbox"/>

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12	SUMMERTON, James, "Morpholino antisense oligomers: the case for an RNase H-independent structural type," Biochimica et Biophysica Acta, Vol. 1489:141-158 (1999) (Exhibit Number 1038 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
13	Supplementary European Search Report for Application No. 10829367.1, 8 pages, dated May 22, 2013	<input type="checkbox"/>
14	Suter et al., "Double-target antisense U7 snRNAs promote efficient skipping of an aberrant exon in three human Beta-thalassemic mutations," 8:13 HUMAN MOLECULAR GENETICS 2415-2423 (1999) (Exhibit Number 1083 filed in interferences 106008, 106007 on December 23, 2014)	<input type="checkbox"/>
15	T HOEN, Peter A.C. et al., "Generation and Characterization of Transgenic Mice with the Full-length Human DMD Gene," The Journal of Biological Chemistry, Vol. 283(9):5899-5907 (2008) Exhibit Number 2030 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
16	Table 1: Primer and Product Details for Exon 51 and 53 Reports on AONs of 20 to 50 Nucleotides dd 07 JAN 2015, Pages 1, Exhibit Number 1177 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
17	Takeshima et al., "Oligonucleotides against a splicing enhancer sequence led to dystrophin production in muscle cells from a Duchenne muscular dystrophy patient," Brain & Dev., Vol. 23, pp. 788-790 (2001), Exhibit Number 1196 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
18	TAKESHIMA, Yasuhiro et al., "Modulation of In Vitro Splicing of the Upstream Intron by Modifying an Intra-Exon Sequence Which Is Deleted from the Dystrophin Gene in Dystrophin Kobe," J. Clin. Invest., Vol. 95:515-520 (1995)	<input type="checkbox"/>
19	TANAKA, Kenji et al., "Polypurine Sequences within a Downstream Exon Function as a Splicing Enhancer," Molecular and Cellular Biology, Vol. 14(2):1347-1354 (1994)	<input type="checkbox"/>
20	THANH, Le Thiet et al., "Characterization of Revertant Muscle Fibers in Duchenne Muscular Dystrophy, Using Exon-Specific Monoclonal Antibodies against Dystrophin," Am. J. Hum. Genet., Vol. 56:725-731 (1995)	<input type="checkbox"/>
21	The Regents of the University of California v. Dako North America, Inc., U.S.D.C., N.D. California, No. C05-03955 MHP, April 22, 2009 (2009 WL 1083446 (N.D.Cal.), Exhibit Number 1206 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
22	TIAN, Xiaobing et al., "Imaging Oncogene Expression," Ann. N.Y. Acad. Sci., Vol. 1002:165-188 (2003) (Exhibit Number 2029 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>

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23	Transcript of 2nd Deposition of Erik J. Sontheimer, Ph.D., dated March 12, 2015, (Academisch Ziekenhuis Leiden Exhibit 1231, filed April 3, 2015 in Interference 106007 and 106008, pages 1-185).	<input type="checkbox"/>
24	Transcript of 2nd Deposition of Matthew J.A. Wood, M.D., D. Phil, dated March 5, 2015, (Academisch Ziekenhuis Leiden Exhibit 1230, filed April 3, 2015 in Interference 106007 and 106008, pages 1-117).	<input type="checkbox"/>
25	Transcript of December 12, 2014 Teleconference with Administrative Patent Judge Schafer (rough draft) (previously filed in Int. No. 106,008 as Ex. 2114), Pages 28 Exhibit Number 1001 filed in Interference 106,013 on February 17, 2015.	<input type="checkbox"/>
26	Transcript of the January 21, 2015 deposition of Erik Sontheimer, Ph.D., Patent Interference Nos. 106,007 and 106,008, 98 pages, dated January 21, 2015 (Exhibit Number 2122 filed in interferences 106,007 and 106,008 on February 17, 2015).	<input type="checkbox"/>
27	Transcript of the March 11, 2015 deposition of Judith van Deutekom, Ph.D., (University of Western Australia Exhibit 2141, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-168).	<input type="checkbox"/>
28	Transcript of the March 12, 2015 deposition of Erik J. Sontheimer, Ph.D., (University of Western Australia Exhibit 2142, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-183).	<input type="checkbox"/>
29	Transcript of the March 5, 2015 deposition of Matthew J. A. Wood, M.D., D. PHIL., (University of Western Australia Exhibit 2146, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-115).	<input type="checkbox"/>
30	Transfection of AON, Pages 1, Exhibit Number 1170 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
31	U.S. Food and Drug Administration Statement, dated December 30, 2014 (2 pages), Exhibit Number 1204 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
32	U.S. Patent Application No. 12/198,007, as-filed August 25, 2008 ("the '007 Application") (Exhibit Number 1073 filed in interferences 106008, 106007 on December 23, 2014)	<input type="checkbox"/>
33	U.S. Patent Application No. 12/976,381, as-filed December 22, 2010 ("the '381 Application") (Exhibit Number 1074 filed in interferences 106008, 106007 on December 23, 2014)	<input type="checkbox"/>

**INFORMATION DISCLOSURE
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Application Number	14214480
Filing Date	2014-03-14
First Named Inventor	Richard K. BESTWICK
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Examiner Name	D. H. Shin
Attorney Docket Number	AVN-013B

34	U.S. Patent Application Publication No. 2001/0056077 ("Matsuo") 10 pages, (Exhibit Number 1080 filed in interferences 106008, 106007 on December 23, 2014)	<input type="checkbox"/>
35	U.S. Patent Application Publication No. 2002/0049173 ("Bennett et al."), 50 pages, (Exhibit Number 1081 filed in interferences 106008, 106007 on December 23, 2014)	<input type="checkbox"/>
36	U.S. Patent No. 5,190,931 ("the '931 Patent") 22 pages, (Exhibit Number 1069 filed in interferences 106008, 106007 on December 23, 2014)	<input type="checkbox"/>
37	U.S. Patent No. 7,001,761 (the "Xiao" Patent), 64 pages, (Exhibit Number 1070 filed in interferences 106008, 106007 on December 23, 2014)	<input type="checkbox"/>
38	University of Western Australia Objections to Opposition Evidence, served on February 24, 2015 filed in Interference No. 106,007, Exhibit 2150, filed April 10, 2015 in Interference Nos. 106007 and 106008, pages 1-15.	<input type="checkbox"/>
39	University of Western Australia Objections to Opposition Evidence, served on February 24, 2015, filed in Interference No. 106,008, Exhibit 2151, filed April 10, 2015, in Interference Nos. 106007 and 106008, pages 1-15.	<input type="checkbox"/>
40	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden List of Exhibits (as of Apr. 3, 2015), filed in Patent Interference No. 106,007, April 3, 2015, pages 1-18, (Doc 423).	<input type="checkbox"/>
41	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden List of Exhibits (as of Apr. 3, 2015), filed in Patent Interference No. 106,008, April 3, 2015, pages 1-18 (Doc 435).	<input type="checkbox"/>
42	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden List of Exhibits, 18 pages, Patent Interference No. 106,007, (Doc 391), dated February 17, 2015.	<input type="checkbox"/>
43	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden List of Exhibits, 18 pages, Patent Interference No. 106,008, (Doc 398), dated February 17, 2015.	<input type="checkbox"/>
44	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden List of Exhibits, 3 pages, Patent Interference No. 106,013, (Doc 147), dated February 17, 2015.	<input type="checkbox"/>

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Application Number # 36339	14214480
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Examiner Name	D. H. Shin
Attorney Docket Number	AVN-013B

45	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Notice of Service of Supplemental Evidence, 3 pages, Patent Interference No. 106,007 (Doc 414), dated March 9, 2015.	<input type="checkbox"/>
46	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Notice of Service of Supplemental Evidence, 3 pages, Patent Interference No. 106,008 (Doc 422), dated March 9, 2015.	<input type="checkbox"/>
47	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Opposition 1 (35 U.S.C. § 112(a)), 83 pages, Patent Interference No. 106,008, (Doc 400), dated February 17, 2015	<input type="checkbox"/>
48	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Opposition 1 (35 U.S.C. § 112(a)), 93 pages, Patent Interference No. 106,007, (Doc 392), dated February 17, 2015	<input type="checkbox"/>
49	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Opposition 1 (Standing Order ¶ 203.1 and 37 C.F.R. § 41.202(a) and (e)), 20 pages, Patent Interference No. 106,013, (Doc 148), dated February 17, 2015	<input type="checkbox"/>
50	University of Western Australia v. Academisch Ziekenhuis Leiden, Academisch Ziekenhuis Leiden Opposition 2 (Indefiniteness), 31 pages, Patent Interference No. 106,007, (Doc 396), dated February 17, 2015	<input type="checkbox"/>

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	Art Unit	1674	
	Examiner Name	D. H. Shin	
	Attorney Docket Number	AVN-013B	

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	1	9018368		2015-04-28	Wilton et al.	
	2	9024007		2015-05-05	Wilton et al.	
	3	9035040		2015-05-19	Wilton et al.	

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	1	20130116310	A1	2013-05-09	Wilton et al.	
	2	20130217755	A1	2013-08-22	WILTON et al.	
	3	20130253033	A1	2013-09-26	WILTON et al.	

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2014-03-14

First Named Inventor

Richard K. BESTWICK

Art Unit

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Examiner Name

D. H. Shin

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4	20130253180	A1	2013-09-26	WILTON et al.	
5	20130274313	A1	2013-10-17	WILTON et al.	
6	20130331438	A1	2013-12-12	WILTON et al.	
7	20140080898	A1	2014-03-20	Wilton et al.	
8	20140094500	A1	2014-04-03	SAZANI et al.	
9	20140155587	A1	2014-06-05	WILTON et al.	
10	20140243515	A1	2014-08-28	WILTON et al.	
11	20140243516	A1	2014-08-28	WILTON et al.	
12	20140315862	A1	2014-10-23	Kaye	
13	20140315977	A1	2014-10-23	BESTWICK et al.	
14	20140323544	A1	2014-10-30	BESTWICK et al.	

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15	20140329762	A1	2014-11-06	KAYE	
16	20140329881	A1	2014-11-06	Bestwick et al.	
17	20140350067	A1	2014-11-27	Wilton et al.	
18	20150152415	A1	2015-06-04	SAZANI et al.	
19	20150045413	A1	2015-02-12	De Visser et al.	

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	1	2014/144978	WO	A2	2014-09-18	Sarepta Therapeutics, Inc		<input type="checkbox"/>

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	1	"Efficacy Study of AVI-4658 to Induce Dystrophin Expression in Selected Duchenne Muscular Dystrophy Patients" ClinicalTrials.gov dated January 22, 2013	<input type="checkbox"/>

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2	"Efficacy Study of AVI-4658 to Induce Dystrophin Expression in Selected Duchenne Muscular Dystrophy Patients," Clinical Trial Identifier No. NCT01396239, ClinicalTrials.gov, dated July, 15, 2011, page 1-4.	<input type="checkbox"/>
3	"Eteplirsen - Inhibitor of Dystrophin Expression - Treatment of Duchenne Muscular Dystrophy", Drugs of the Future, Vol.38(1):13-17 (2013)	<input type="checkbox"/>
4	2nd Expert Declaration of Dr. Erik Sontheimer ("2nd S Decl.") (Exhibit Number 1067 filed in interferences 106008, 106007 on December 23, 2014)	<input type="checkbox"/>
5	3rd Declaration of Erik J. Sontheimer, Ph.D. ("3rd S. Decl."), Pages 123, Exhibit Number 1186 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
6	A Comparative Study on AONs between 20 and 50 Nucleotides Designed to Induce the Skipping of Exon 53 from the Dystrophin Pre-mRNA, Pages 6, Exhibit Number 1128 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
7	A Comparative Study on AONs Between 20 and 50 Nucleotides Designed to Induce the Skipping of Exon 51 from the Dystrophin Pre-mRNA, Pages 6, Exhibit Number 1127 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
8	Aartsma-Rus A, et al. "Theoretic applicability of antisense-mediated exon skipping for Duchenne muscular dystrophy mutations," Hum Mutat 2009;30:293-99.	<input type="checkbox"/>
9	Aartsma-Rus et al., "Antisense-induced exon skipping for duplications in Duchenne muscular dystrophy," BMC Medical Genetics 8:43 (2007), (University of Western Australia Exhibit 2135, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-9.)	<input type="checkbox"/>
10	AARTSMA-RUS, Annemieke et al., "194th ENMC international workshop. 3rd ENMC workshop on exon skipping: Towards clinical application of antisense-mediated exon skipping for Duchenne muscular dystrophy 8-10 December 2012, Naarden, The Netherlands," Neuromuscular Disorders, Vol. 23:934-944 (2013)	<input type="checkbox"/>
11	Sarepta, "Sarepta Therapeutics Announces Eteplirsen Demonstrates Continued Stability on Walking Test through 120 Weeks in Phase IIB Study in Duchenne Muscular Dystrophy," press release, 3 pages, dated January 15, 2014 (Exhibit Number 2034 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
12	AARTSMA-RUS, Annemieke et al., "Antisense-Induced Multiexon Skipping for Duchenne Muscular Dystrophy Makes More Sense," Am. J. Hum. Genet., Vol. 74:83-92 (2004)	<input type="checkbox"/>

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13	AARTSMA-RUS, Annemieke et al., "Functional Analysis of 114 Exon-Internal AONs for Targeted DMD Exon Skipping: Indication for Steric Hindrance of SR Protein Binding Sites," Oligonucleotides, Vol. 15:284-297 (2005) (Exhibit Number 2016 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
14	AARTSMA-RUS, Annemieke et al., "Guidelines for Antisense Oligonucleotide Design and Insight Into Splice-modulating Mechanisms," Molecular Therapy, Vol. 17(3):548-553 (2009) (Exhibit Number 2014 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
15	AARTSMA-RUS, Annemieke et al., "Targeted exon skipping as a potential gene correction therapy for Duchenne muscular dystrophy," Neuromuscular Disorders, Vol. 12:S71-S77 (2002)	<input type="checkbox"/>
16	AARTSMA-RUS, Annemieke et al., "Therapeutic antisense-induced exon skipping in cultured muscle cells from six different DMD patients," Human Molecular Genetics, Vol. 12(8):907-914 (2003)	<input type="checkbox"/>
17	ABBS, Stephen et al., "A convenient multiplex PCR system for the detection of dystrophin gene deletions: a comparative analysis with cDNA hybridisation shows mistypings by both methods," J. Med. Genet., Vol. 28:304-311 (1991)	<input type="checkbox"/>
18	Abes, S. et al., "Efficient Splicing Correction by PNA Conjugation to an R6-Penetratin Delivery Peptide", Nucleic Acids Research Vol.35(13):4495-4502 (2007)	<input type="checkbox"/>
19	AGRAWAL, Sudhir et al., "GEM 91 - An Antisense Oligonucleotide Phosphorothioate as a Therapeutic Agent for AIDS," Antisense Research and Development, Vol. 2:261-266 (1992)	<input type="checkbox"/>
20	AGRAWAL, Sudhir et al., "Oligodeoxynucleoside phosphoramidates and phosphorothioates as inhibitors of human immunodeficiency virus," Proc. Natl. Acad. Sci. USA, Vol. 85:7079-7083 (1988)	<input type="checkbox"/>
21	Ahmad A, et al., "Mdx mice inducibly expressing dystrophin provide insights into the potential of gene therapy for Duchenne muscular dystrophy," Hum Mol Genet 2000;9:2507-2515.	<input type="checkbox"/>
22	AKHTAR, Saghir et al., "Cellular uptake and intracellular fate of antisense oligonucleotides," Trends in Cell Biology, Vol. 2:139-144 (1992)	<input type="checkbox"/>
23	AKHTAR, Saghir, "Delivery Strategies for Antisense Oligonucleotide Therapeutics," CRC Press, Inc., Boca Raton, FL, 160 pages (1995)	<input type="checkbox"/>

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24	Alignments of Dystrophin mRNA and Oligonucleotides, 6 pages, submitted to the Patent Trial and Appeal Board in interference No. 106008, dated November 18, 2014 (Exhibit Number 1054 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
25	ALTER, Julia et al., "Systemic delivery of morpholino oligonucleotide restores dystrophin expression bodywide and improves dystrophic pathology," Nature Medicine, Vol. 12(2):175-177 (2006)	<input type="checkbox"/>
26	Amendment under 37 CFR 1.312 for Application No. 14/248,279, 5 pages, dated September 19, 2014 (Exhibit Number 2053 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
27	Analysis of Second PCR Product by Gel Electrophoresis, Pages 1, Exhibit Number 1182 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
28	ANDERSON, W. French, "Human Gene Therapy," Science, Vol. 256:808-813 (1992)	<input type="checkbox"/>
29	Annotated scenario introduced and referred to during March 12, 2015; deposition of Erik J. Sontheimer, Ph.D., (University of Western Australia Exhibit 2139, filed April 3, 2015 in Interferences 106007, 106008, and 106013, page 1.	<input type="checkbox"/>
30	ANTHONY, Karen et al., "Dystrophin quantification: Biological and Translational Research Implications," Neurology, Vol. 83:1-8 (2014) (Exhibit Number 2028 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
31	AON PS1958 Mass Spectrometry Data, Pages 7, Exhibit Number 1146 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
32	AON PS1958 UPLC Data, Pages 2, Exhibit Number 1157 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
33	AON PS1959 Mass Spectrometry Data, Pages 5, Exhibit Number 1147 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
34	AON PS1959 UPLC Data, Pages 2, Exhibit Number 1158 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>

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35	AON PS1960 Mass Spectrometry Data, Pages 8, Exhibit Number 1148 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
36	AON PS1960 UPLC Data, Pages 2, Exhibit Number 1159 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
37	AON PS1961 Mass Spectrometry Data, Pages 5, Exhibit Number 1149 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
38	AON PS1961 UPLC Data, Pages 2, Exhibit Number 1160 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
39	AON PS1962 Mass Spectrometry Data, Pages 7, Exhibit Number 1150 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
40	AON PS1962 UPLC Data, Pages 2, Exhibit Number 1161 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
41	AON PS1963 Mass Spectrometry Data, Pages 10, Exhibit Number 1151 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
42	AON PS1963 UPLC Data, Pages 2, Exhibit Number 1162 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
43	AON PS1964 Mass Spectrometry Data, Pages 13, Exhibit Number 1152 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
44	AON PS1964 UPLC Data, Pages 2, Exhibit Number 1163 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
45	AON PS1965 Mass Spectrometry Data, Pages 9, Exhibit Number 1153 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>

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46	AON PS1965 UPLC Data, Pages 2, Exhibit Number 1164 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
47	AON PS1966 Mass Spectrometry Data, Pages 8, Exhibit Number 1154 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
48	AON PS1966 UPLC Data, Pages 2, Exhibit Number 1165 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
49	AON PS1967 Mass Spectrometry Data, Pages 7, Exhibit Number 1155 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
50	AON PS1967 UPLC Data, Pages 2, Exhibit Number 1166 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>

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1	US 8,759,307 (Stein et al.), Pages 35, Exhibit Number 1101 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
2	US 8,779,128 (Hanson et al.), Pages 104, Exhibit Number 1102 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
3	US 8,785,407 (Stein et al.), Pages 35, Exhibit Number 1103 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
4	US 8,785,410 (Iversen et al.), Pages 20, Exhibit Number 1104 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
5	US 8,835,402 (Kole et al.), Pages 27, Exhibit Number 1105 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
6	US 8,865,883 (Sazani et al.), Pages 199, Exhibit Number 1106 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
7	US 8,871,918 (Sazani et al.), Pages 195, Exhibit Number 1107 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
8	US 8,877,725 (Iversen et al.), Pages 34, Exhibit Number 1108 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
9	US 8,895,722 (Iversen et al.), Pages 29, Exhibit Number 1109 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
10	US 8,906,872 (Iversen et al.), Pages 69, Exhibit Number 1110 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
11	US Abandonment for Application No. 13/902,376, 1 page, dated June 12, 2014 (Exhibit Number 1047 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>

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12	US Amendment After Non-Final Action for Application No. 11/233,495, 31 pages, dated June 24, 2010 (Exhibit Number 2073 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
13	US Amendment for Application No. 11/233,495, 15 pages, dated April 1, 2009 (Exhibit Number 2071 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
14	US Amendment for Application No. 11/233,495, 19 pages, dated September 16, 2009 (Exhibit Number 2072 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
15	US Amendment for Application No. 11/233,495, 9 pages, dated October 31, 2007 (Exhibit Number 2070 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
16	US Amendment for Application No. 11/570,691, 9 pages, dated June 15, 2010 (Exhibit Number 1043 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
17	US Amendment for Application No. 13/271,080, 30 pages, dated January 30, 2013 (Exhibit Number 1049 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
18	US Amendment for Application No. 13/902,376, 36 pages, dated March 21, 2014 (Exhibit Number 1046 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
19	US Amendment in Response to Advisory Action for Application No. 11/233,495, 23 pages, dated March 14, 2011 (Exhibit Number 2074 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
20	US Amendments to the Claims for Application No. 11/233,495, 4 pages, dated May 8, 2014 (Exhibit Number 2077 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
21	US Amendments to the Claims for Application No. 14/198,992, 3 pages, dated July 16, 2014 (Exhibit Number 2079 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
22	US Applicant-Initiated Interview Summary and Notice of Allowance for Application No. 13/550,210, 9 pages dated May 19, 2014 (Exhibit Number 2076 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>

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Application Number	14214480
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First Named Inventor	Richard K. BESTWICK
Art Unit	1674
Examiner Name	D. H. Shin
Attorney Docket Number	AVN-013B

23	US application as-filed and Preliminary Amendment for Application No. 13/550,210, 59 pages dated July 16, 2012 (Exhibit Number 2087 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
24	US Application as-filed for application No. 14/198,992, 52 pages, dated March 6, 2014 (Exhibit Number 2086 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
25	US Application as-filed, Application Data Sheet, and Preliminary Amendment for Application No. 12/837,359, 101 pages, dated July 15, 2010 (Exhibit Number 2100 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
26	US Application for Letters Patent for Application No. 11/233,495 as-filed and preliminary amendment, 77 pages, dated September 21, 2005 (Exhibit Number 2095 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
27	US Application No. 11/233,495, 74 pages; excerpts of prosecution history including: US Supplemental Amendment and Response dated May 8, 2014; Second Supplemental Response dated July 25, 2013; Supplemental Amendment dated June 26, 2013; Amendment after Non-final Action dated November 1, 2010; Amendment under 35 USC 1.114 dated September 16, 2009 (Exhibit Number 2054 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
28	US Application No. 14/198,992, 17 pages; excerpts of prosecution history including: Supplemental Amendment dated July 16, 2014; Response to Non-Final Office Action dated July 14, 2014 (Exhibit Number 2056 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
29	US Application No. 14/248,279, 29 pages; excerpts of prosecution history including: Amendment under 37 CFR 1.312 dated September 19, 2014; Amendment in Response to Final Office Action dated August 7, 2014; Declaration under 37 CFR 1.132 dated May 26, 2014; Declaration under 37 CFR 1.132 dated May 27, 2014; Response dated June 3, 2014 (Exhibit Number 2057 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
30	US Application No.13/550,210, 27 pages; excerpts of prosecution history including: Response and Amendment dated May 12, 2014; Response to Non-Final Office Action dated January 21, 2014; Second Preliminary Amendment dated January 3, 2013 (Exhibit Number 2055 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
31	US Claim amendments for Application No. 13/550,210, 3 pages, dated May 12, 2014 (Exhibit Number 2078 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
32	US Claims for Application No. 12/976,381, 1 page, dated December 22, 2010 (Exhibit Number 2065 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
33	US Declaration of Richard K. Bestwick, for Application No. 11/570,691, 5 pages, dated June 15, 2010 (Exhibit Number 1044 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>

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34	US E-mail from Patent Trial and Appeal Board to Danny Huntington, 2 pages, dated October 9, 2014 (Exhibit Number 2002 filed in interferences 106008 on October 17, 2014)	<input type="checkbox"/>
35	US Non-Final Office Action for Application No. 11/570,691, 16 pages, dated March 15, 2010 (Exhibit Number 1042 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
36	US Office Action for Application No. 13/271,080, 25 pages, dated July 30, 2012 (Exhibit Number 1048 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
37	US Office Action for Application No. 13/550,210, 12 pages, dated September 27, 2013 (Exhibit Number 2080 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
38	US Office Action for Application No. 13/902,376, 7 pages, dated January 7, 2014 (Exhibit Number 1045 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
39	US Patent Application No. 12/198,007 as-filed, 64 pages, dated August 25, 2008 (Exhibit Number 2092 filed in interferences 106008, 106013, and 106007 on November 18, 2014)	<input type="checkbox"/>
40	US Preliminary Amendment and application as-filed for Application No. 12/976,381, 64 pages, dated December 22, 2010 (Exhibit No. 2089 filed in Interferences 106007, 106008, and 106013 on November 18, 2014)	<input type="checkbox"/>
41	US Preliminary Amendment for Application No. 11/233,495, 10 pages, dated September 21, 2005 (Exhibit Number 2069 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
42	US Preliminary Remarks for Application No. 14/198,992, 1 page, dated March 6, 2014 (Exhibit Number 2097 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
43	US Proposed Terminal Disclaimer for Application No. 12/860,078, 2 pages, dated October 17, 2014 (Exhibit Number 2001 filed in interference 106008 on October 17, 2014)	<input type="checkbox"/>
44	US Remarks for Application No. 14/248,279, 2 pages, dated August 27, 2014 (Exhibit Number 2110 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>

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45	US Response and amendments for Application No. 13/550,210, 12 pages, dated January 21, 2014 (Exhibit Number 2063 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
46	US Revised Figure 4H, US Application No. 13/271,080, 1 page (Exhibit Number 1050 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
47	US Terminal Disclaimer for Application No. 14/198,992, 1 page, dated July 15, 2014 (Exhibit Number 2096 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
48	US Terminal Disclaimer for Application No. 14/248,279, 1 page, dated August 7, 2014 (Exhibit Number 2109 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
49	US Track One Request, Application as-filed, and Application Data Sheet for Application No. 14/248,279, 68 pages, dated April 8, 2014 (Exhibit Number 2108 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
50	US Transmittal, application as-filed, and Preliminary Amendment for Application No. 11/570,691, 102 pages, dated December 15, 2006 (Exhibit Number 2103 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>

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1	LIU, Hong-Xiang et al., "Identification of functional exonic splicing enhancer motifs recognized by individual SR proteins," Genes & Development, Vol. 12:1998-2012 (1998)	<input type="checkbox"/>
2	Lu et al., "Massive Idiosyncratic Exon Skipping Corrects the Nonsense Mutation in Dystrophic Mouse Muscle and Produces Functional Revertant Fibers by Clonal Expansion," THE JOURNAL OF CELL BIOLOGY, Vol. 148(5): 985-995, March 6, 2000 ("Lu et al.") (Exhibit Number 1082 filed in interferences 106008, 106007 on December 23, 2014)	<input type="checkbox"/>
3	LU, Qi Long et al., "Functional amounts of dystrophin produced by skipping the mutated exon in the mdx dystrophic mouse," Nature Medicine, Vol. 9(8):1009-1014 (2003)	<input type="checkbox"/>
4	LU, Qi-long et al., "What Can We Learn From Clinical Trials of Exon Skipping for DMD?" Molecular Therapy - Nucleic Acids, Vol. 3:e152, doi:10.1038/mtna.2014.6, 4 pages (2014)	<input type="checkbox"/>
5	Lyophilisation of Oligonucleotides, Pages 2, Exhibit Number 1133 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
6	MANN, Christopher J. et al., "Antisense-induced exon skipping and synthesis of dystrophin in the mdx mouse," PNAS, Vol. 98(1):42-47 (2001)	<input type="checkbox"/>
7	MANN, Christopher J. et al., "Improved antisense oligonucleotide induced exon skipping in the mdx mouse model of muscular dystrophy," The Journal of Gene Medicine, Vol. 4:644-654 (2002)	<input type="checkbox"/>
8	MANNINO, Raphael J. et al., "Liposome Mediated Gene Transfer," BioTechniques, Vol. 6(7):682-690 (1988)	<input type="checkbox"/>
9	Manual of Patent Examining Procedure 2308.02 (6th ed., rev. 3, July 1997), (University of Western Australia Exhibit 2143, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-2).	<input type="checkbox"/>
10	Manzur A, et al., "Glucocorticoid corticosteroids for Duchenne muscular dystrophy," Cochrane Database Syst Rev. 2004;(2):CD003725.	<input type="checkbox"/>
11	MARSHALL, N.B. et al., "Arginine-rich cell-penetrating peptides facilitate delivery of antisense oligomers into murine leukocytes and alter pre-mRNA splicing," Journal of Immunological Methods, Vol. 325:114-126 (2007)	<input type="checkbox"/>

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12	Mathews et al., "Expanded Sequence Dependence of Thermodynamic Parameters Improves Prediction of RNA Secondary Structure," J. Mol. Biol. 288:911-940 (1999), (University of Western Australia Exhibit 2131, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-31).	<input type="checkbox"/>
13	Mathews et al., "Expanded Sequence Dependence of Thermodynamic Parameters Improves Prediction of RNA Secondary Structure," J. Mol. Biol., Vol. 288, pp. 911-940 (1999), Exhibit Number 1212 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
14	MATSUO, Masafumi et al., "Exon Skipping during Splicing of Dystrophin mRNA Precursor due to an Intraexon Deletion in the Dystrophin Gene of Duchenne Muscular Dystrophy Kobe," J. Clin. Invest., Vol. 87:2127-2131 (1991)	<input type="checkbox"/>
15	MATSUO, Masafumi et al., "Treatment of Duchenne Muscular Dystrophy with Oligonucleotides against an Exonic Splicing Enhancer Sequence," Basic Appl. Myol., Vol. 13(6):281-285 (2003)	<input type="checkbox"/>
16	MATSUO, Masafumi, "Duchenne and Becker Muscular Dystrophy: From Gene Diagnosis to Molecular Therapy," IUBMB Life, Vol. 53:147-152 (2002)	<input type="checkbox"/>
17	MATSUO, Masafumi, "Duchenne/Becker muscular dystrophy: from molecular diagnosis to gene therapy," Brain & Development, Vol. 18:167-172 (1996)	<input type="checkbox"/>
18	MATTEUCCI, Mark, "Structural modifications toward improved antisense oligonucleotides," Perspectives in Drug Discovery and Design, Vol. 4:1-16 (1996)	<input type="checkbox"/>
19	Mazzone E, et al. "Functional changes in Duchenne muscular dystrophy: a 12-month longitudinal cohort study," Neurology 2011;77(3):250-6.	<input type="checkbox"/>
20	MCCARVILLE, M. Beth et al., "Rhabdomyosarcoma in Pediatric Patients: The Good, the Bad, and the Unusual," AJR, Vol. 176:1563-1569 (2001) (Exhibit Number 1034 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
21	MCCLOREY, G. et al., "Antisense oligonucleotide-induced exon skipping restores dystrophin expression in vitro in a canine model of DMD," Gene Therapy, Vol. 13:1373-1381 (2006)	<input type="checkbox"/>
22	MCCLOREY, G. et al., "Induced dystrophin exon skipping in human muscle explants," Neuromuscular Disorders, Vol. 16:583-590 (2006)	<input type="checkbox"/>

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23	McCLOREY, Graham et al., "Splicing intervention for Duchenne muscular dystrophy," Current Opinion in Pharmacology, Vol. 5:529-534 (2005)	<input type="checkbox"/>
24	McDonald CM, et al., "Profiles of Neuromuscular Diseases, Duchenne muscular dystrophy," Am J Phys Med Rehabil 1995;74:S70-S92	<input type="checkbox"/>
25	McDonald CM, et al., "The 6-minute walk test as a new outcome measure in Duchenne muscular dystrophy," Muscle Nerve 2010;41:500-10.	<input type="checkbox"/>
26	McDonald CM, et al., "The 6-minute walk test in Duchenne/Becker muscular dystrophy: longitudinal observations," Muscle Nerve 2010;42: 966-74.	<input type="checkbox"/>
27	Mendell JR et al., "Evidence-based path to newborn screening for Duchenne muscular Dystrophy," Ann Neurol 2012;71:304-13.	<input type="checkbox"/>
28	Mendell JR, et al., "Dystrophin immunity revealed by gene therapy in Duchenne muscular dystrophy," N Engl J Med 2010;363:1429-37.	<input type="checkbox"/>
29	Mendell JR, et al., "Randomized, double-blind six-month trial of prednisone in Duchenne's muscular dystrophy," N Engl J Med 1989;320:1592-97.	<input type="checkbox"/>
30	MENDELL, Jerry R. et al., "Eteplirsen for the Treatment of Duchenne Muscular Dystrophy," Ann. Neurol., Vol. 74:637-647 (2013) (Exhibit Number 2058 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
31	MENDELL, Jerry R. et al., "Eteplirsen in Duchenne Muscular Dystrophy (DMD): 144 Week Update on Six-Minute Walk Test (6MWT) and Safety," slideshow, presented at the 19th International Congress of the World Muscle Society, 17 pages (2014) (Exhibit Number 2059 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
32	MENDELL, Jerry R. et al., "Gene therapy for muscular dystrophy: Lessons learned and path forward," Neuroscience Letters, Vol. 527:90-99 (2012)	<input type="checkbox"/>
33	Merlini L, et al., "Early corticosteroid treatment in 4 Duchenne muscular dystrophy patients: 14-year follow-up," Muscle Nerve 2012;45:796-802.	<input type="checkbox"/>

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34	Mfold illustrations for Exon 51 and Exon 53 with varying amounts of intron sequence, (University of Western Australia Exhibit 2132, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-2).	<input type="checkbox"/>
35	MITRPANT, Chalermchai et al., "Rational Design of Antisense Oligomers to Induce Dystrophin Exon Skipping," Molecular Therapy, Vol. 17(8):1418-1426 (2009)	<input type="checkbox"/>
36	MONACO, Anthony P. et al., "An Explanation for the Phenotypic Differences between Patients Bearing Partial Deletions of the DMD Locus," Genomics, Vol. 2:90-95 (1988)	<input type="checkbox"/>
37	Morcos, Paul A., "Gene switching: analyzing a broad range of mutations using steric block antisense oligonucleotides," Methods in Enzymology, Vol. 313:174-189 (1999)	<input type="checkbox"/>
38	MOULTON, H.M., "Compound and Method for Treating Myotonic Dystrophy," U.S. Application No. 12/493,140, 82 pages, filed June 26, 2009	<input type="checkbox"/>
39	MOULTON, Hong M. et al., "Morpholinos and their peptide conjugates: Therapeutic promise and challenge for Duchenne muscular dystrophy," Biochimica et Biophysica Acta, Vol. 1798:2296-2303 (2010)	<input type="checkbox"/>
40	Muntoni F, et al., "Dystrophin and mutations: one gene, several proteins, multiple phenotypes," Lancet Neurol. 2003;2:731-40.	<input type="checkbox"/>
41	MUNTONI, Francesco et al., "128th ENMC International Workshop on 'Preclinical optimization and Phase I/II Clinical Trials Using Antisense Oligonucleotides in Duchenne Muscular Dystrophy' 22-24 October 2004, Naarden, The Netherlands," Neuromuscular Disorders, Vol. 15:450-457 (2005) (Exhibit Number 2025 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
42	MUNTONI, Francesco et al., "149th ENMC International Workshop and 1st TREAT-NMD Workshop on: 'Planning Phase I/II Clinical trials using Systemically Delivered Antisense Oligonucleotides in Duchenne Muscular Dystrophy,'" Neuromuscular Disorders, Vol. 18:268-275 (2008)	<input type="checkbox"/>
43	NELSON, David L. et al., "Nucleotides and Nucleic Acids," Lehninger Principles of Biochemistry, 3rd Edition, Chapter 10, pages 325-328 and glossary page G-11, Worth Publishers, New York (2000)	<input type="checkbox"/>
44	Nguyen TM, et. Al., "Use of Epitope libraries to identify exon-specific monoclonal antibodies for characterization of altered dystrophins in muscular dystrophy," Am J Hum Genet 1993;52:1057-66.	<input type="checkbox"/>

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Application Number # 36359	14214480
Filing Date	2014-03-14
First Named Inventor	Richard K. BESTWICK
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45	Oberbauer, "Renal uptake of an 18-mer phosphorothioate oligonucleotide," Kidney Int'l, Vol. 48, pp. 1226-1232 (1995), Exhibit Number 1191 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
46	Oligonucleotide Cleavage and Deprotection Laboratory Notebook Entry, Pages 1, Exhibit Number 1138 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
47	Oligonucleotide diagrams, 5 pages (Exhibit Number 1053 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
48	Partial European Search Report for Application No. 10004274.6, 6 pages, dated October 2, 2012	<input type="checkbox"/>
49	Partial European Search Report for Application No. 12162995.0, 6 pages, dated October 2, 2012	<input type="checkbox"/>
50	Patentee's Response to European Patent Application No. 05076770.6, dated July 28, 2006, 4 pages	<input type="checkbox"/>

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1	University of Western Australia v. Academisch Ziekenhuis Leiden, Statement Concerning Subsequent Settlement Discussions, filed in Patent Interference No. 106,013, August 24, 2015, pages 1-3 (Doc 195).	<input type="checkbox"/>
2	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Recent Authority, filed in Patent Interference No. 106,007, September 2, 2015, pages 1-18 (Doc 470).	<input type="checkbox"/>
3	University of Western Australia v. Academisch Ziekenhuis Leiden, UWA Notice of Recent Authority, filed in Patent Interference No. 106,008, September 2, 2015, pages 1-18 (Doc 478).	<input type="checkbox"/>

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	Filing Date		2014-03-14	
	First Named Inventor	Richard K. BESTWICK		
	Art Unit	1674		
	Examiner Name	D. H. Shin		
	Attorney Docket Number	AVN-013B		

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1	Patrick O. Brown and Tidear D. Shalon v. Stephen P.A. Fodor, Dennis W. Solas and William J. Dower: Interference Merits Panel, Interference No. 104,358, 24 pages, dated August 9, 1999 (Exhibit Number 2113 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
2	PCT Application as-filed for application No. PCT/NL03/00214, 71 pages, dated September 21, 2005 (Exhibit Number 2042 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
3	PD-10 Desalting Columns, Pages 12, Exhibit Number 1141 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
4	POPPLEWELL, Linda et al., "Design of phosphorodiamidate morpholino oligmers (PMOs) for the induction of exon skipping of the human DMD gene," Human Gene Therapy 19(10): ESGCT 2008 Poster Presentations, Page 1174, Poster No. P203	<input type="checkbox"/>
5	POPPLEWELL, Linda J. et al., "Comparative analysis of antisense oligonucleotide sequences targeting exon 53 of the human DMD gene: Implications for future clinical trials," Neuromuscular Disorders, Vol. 20(2):102-110 (2010) 9 pages (Exhibit Number 2031 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
6	POPPLEWELL, Linda J. et al., "Design of Antisense Oligonucleotides for Exon Skipping of the Human Dystrophin Gene," Human Gene Therapy 19(4): BSGT 2008 Poster Presentation, Page 407, Poster No. P-35	<input type="checkbox"/>
7	POPPLEWELL, Linda J. et al., "Design of Phosphorodiamidate Morpholino Oligomers (PMOs) for the Induction of Exon Skipping of the Human DMD Gene," Molecular Therapy, Vol. 17(3):554-561 (2009)	<input type="checkbox"/>
8	POPPLEWELL, Linda J. et al., "Targeted Skipping of Exon 53 of the Human DMD Gene Recommendation of the Highly Efficient Antisense Oligonucleotide for Clinical Trial," Human Gene Therapy 20(4): BSGT 2009 Poster Presentations, Page 399, Poster No. P10	<input type="checkbox"/>
9	Poster Abstract Listing for The Tenth Annual Meeting of the RNA Society, held at the Banff Centre for Conferences, in Banff, Alberta, Canada, from May 24-29, 2005, (University of Western Australia Exhibit 2137, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-11).	<input type="checkbox"/>
10	Pramono, "Induction of Exon Skipping of the Dystrophin Transcript in Lymphoblastoid Cells by Transfecting an Antisense Oligodeoxynucleotide Complementary to an Exon Recognition Sequence," Biochem. and Biophy. Res. Comm., Vol. 226, pp. 445-449 (1996), Exhibit Number 1192 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
11	Preliminary Amendment for Application No. 12/976,381, 4 pages, dated December 22, 2010 (Exhibit Number 2066 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>

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12	Preliminary Amendment for Application No. 12/198,007, 3 pages, dated November 7, 2008 (Exhibit Number 2067 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
13	Program Schedule for The Tenth Annual Meeting of the RNA Society, held at the Banff Centre for Conferences, in Banff, Alberta, Canada, from May 24-29, 2005, (University of Western Australia Exhibit 2136, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-4).	<input type="checkbox"/>
14	Proliferation and Differentiation of Myoblast Cultures, Pages 2, Exhibit Number 1169 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
15	Prosensa Press Release, dated October 10, 2014 (2 pages), Exhibit Number 1203 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
16	Prosensa, "GSK and Prosensa Announce Primary Endpoint Not Met in Phase III Study of Drisapersen in Patients With Duchenne Muscular Dystrophy," press release, 4 pages, dated September 20, 2013 (Exhibit Number 2039 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
17	Raz et al. v. Davis et al., Board of Patent Appeals and Interferences, Patent and Trademark Office, Int. No. 105,712, Tech. Ctr. 1600, September 29, 2011 (24 pages) (2011 WL 4568986 (Bd.Pat.App. & Interf.), Exhibit Number 1209 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
18	REESE, Colin B. et al., "Reaction Between 1-Arenesulphonyl-3-Nitro-1,2,4-Triazoles and Nucleoside Base Residues. Elucidation of the Nature of Side-Reactions During Oligonucleotide Synthesis," Tetrahedron Letters, Vol. 21:2265-2268 (1980)	<input type="checkbox"/>
19	REESE, Colin B. et al., "The Protection of Thymine and Guanine Residues in Oligodeoxyribonucleotide Synthesis," J. Chem. Soc. Perkin Trans. 1, pages 1263-1271 (1984)	<input type="checkbox"/>
20	Reexamination Certificate - Application No. 90/011,320, issued March 27, 2012, 2 pages, (Exhibit Number 1072 filed in interferences 106008, 106007 on December 23, 2014)	<input type="checkbox"/>
21	Reply to EPO Communication dated June 26, 2014 in European Application Serial No. 13160338, (University of Western Australia Exhibit 2145, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-4).	<input type="checkbox"/>
22	Reply to EPO Communication dated October 21, 2014 in European Application Serial No. 12198517, (University of Western Australia Exhibit 2148, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-7).	<input type="checkbox"/>

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23	Reply to EPO Communication dated October 23, 2014 in European Application Serial No. 12198485, (University of Western Australia Exhibit 2147, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-8).	<input type="checkbox"/>
24	Response to Office Action and Amendments to the Claims for Application No. 13/550,210, 10 pages, dated May 12, 2014 (Exhibit Number 2064 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
25	Rhodes et al., "BioMarin Bulks Up," BioCentury, pp. 6-8 (December, 2014), Exhibit Number 1193 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
26	RNA Isolation Using RNA-BEE, Pages 1, Exhibit Number 1175 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
27	ROBERTS, Roland G. et al., "Exon Structure of the Human Dystrophin Gene," Genomics, Vol. 16:536-538 (1993)	<input type="checkbox"/>
28	Roest et al., "Application of In Vitro Myo-Differentiation of Non-Muscle Cells to Enhance Gene Expression and Facilitate Analysis of Muscle Proteins," Neuromuscul. Disord., Vol. 6, No. 3, pp. 195-202 (May, 1996), Exhibit Number 1124 filed in interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
29	ROSSO, Mario G. et al., "An Arabidopsis thaliana T-DNA mutagenized population (GABI-Kat) for flanking sequence tag-based reverse genetics," Plant Molecular Biology, Vol. 53:247-259 (2003)	<input type="checkbox"/>
30	Saito, T. et al., "First-in-Human Study of NS-065/NCNP-01; the Morpholino Based Antisense Oligonucleotide for Exon 53 Skipping in Duchenne Muscular Dystrophy," ASGCT meeting, May 13, 2015, Abstract [136] 1 page.	<input type="checkbox"/>
31	Saito, T. et al., "First-in-Human Study of NS-065/NCNP-01; the Morpholino Based Antisense Oligonucleotide for Exon 53 Skipping in Duchenne Muscular Dystrophy," ASGCT meeting, May 13, 2015, pages 1-11.	<input type="checkbox"/>
32		<input type="checkbox"/>
33	Sarepta, "Sarepta Therapeutics Reports Long-Term Outcomes through 144 Weeks from Phase IIb Study of Eteplirsen in Duchenne Muscular Dystrophy," press release, http://investorrelations.sarepta.com/phoenix.zhtml?c=64231&p=irol-newsArticle&id=1946426 , 4 pages, dated July 10, 2014	<input type="checkbox"/>

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34	Scully, Michele et al., "Review of Phase II and Phase III Clinical Trials for Duchenne Muscular Dystrophy", Expert Opinion on Orphan Drugs, Vol.1(1):33-46 (2013)	<input type="checkbox"/>
35	Second Preliminary Amendment filed in US Application No. 13/550,210, 5 pages, dated January 3, 2013 (Exhibit Number 2062 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
36	Second Written Opinion for Application No. PCT/AU2010/001520, 7 pages, dated October 13, 2011	<input type="checkbox"/>
37	Semi Quantitative Lab-on-Chip Analysis of Second PCR Product, Pages 1, Exhibit Number 1183 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
38	Sequence Listing - Serial No. 13/550,210, as filed July 16, 2012 (9 pages), Exhibit Number 1205 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
39	Sequence of Exon 46 of Dystrophin Gene, 1 page	<input type="checkbox"/>
40	Sequence of Exon 51 of Dystrophin Gene, 1 page	<input type="checkbox"/>
41	Shabanpoor et al., "Bi-specific splice-switching PMO oligonucleotides conjugated via a single peptide active in a mouse model of Duchenne muscular dystrophy," Nucleic Acids Res., pp. 1-11 (December, 2014), Exhibit Number 1114 filed in interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
42	SHAPIRO, Marvin B. et al., "RNA splice junctions of different classes of eukaryotes: sequence statistics and functional implications in gene expression," Nucleic Acids Research, Vol. 15(17):7155-7174 (1987)	<input type="checkbox"/>
43	SHERRATT, Tim G. et al., "Exon Skipping and Translation in Patients with Frameshift Deletions in the Dystrophin Gene," Am. J. Hum. Genet., Vol. 53:1007-1015 (1993)	<input type="checkbox"/>
44	SHIGA, Nobuyuki et al., "Disruption of the Splicing Enhancer Sequence within Exon 27 of the Dystrophin Gene by a Nonsense Mutation Induced Partial Skipping of the Exon and Is Responsible for Becker Muscular Dystrophy," J. Clin. Invest., Vol. 100(9):2204-2210 (1997)	<input type="checkbox"/>

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45	SHIMIZU, Miho et al., "Oligo(2'-O-methyl)ribonucleotides Effective probes for duplex DNA," FEBS Letters, Vol. 302 (2):155-158 (1992) (Exhibit Number 1035 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
46	Siemens Healthcare Diagnostics, Inc. v. Enzo Life Sciences, Inc., 2013 WL 4411227, *11 [Parallel cite: U.S.D.C., D. Mass., Civil No. 10-40124-FDS], Decided Aug. 14, 2013 (12 pages); [Cited as: 2013 WL 4411227], Exhibit Number 1210 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
47	SIERAKOWSKA, Halina et al., "Repair of thalassemic human beta-globin mRNA in mammalian cells by antisense oligonucleotides," Proc. Natl. Acad. Sci. USA, Vol. 93:12840-12844 (1996)	<input type="checkbox"/>
48	Sontheimer et al., "Metal ion catalysis during group II intron self-splicing: parallels with the spliceosome," Genes & Development, Vol. 13, pp. 1729-1741 (1999), Exhibit Number 1195 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
49	Sontheimer et al., "Three Novel Functional Variants of Human U5 Small Nuclear RNA," Vol. 12, No. 2, pp. 734-746 (Feb., 1992), Exhibit Number 1194 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
50	SONTHEIMER, Erik J. et al., "Metal ion catalysis during splicing of premessenger RNA," Nature, Vol. 388:801-805 (1997) (Exhibit Number 1036 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>

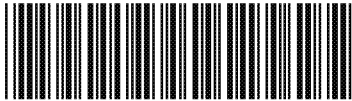
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	Examiner DANA SHIN	Art Unit 1674

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SEARCH NOTES		
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STIC - structure search, results available on SCORE	4-2-2015	DS
EAST	4-10-2015	DS
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PALM - inventor name search	4-14-2015, 10-14-2015	DS

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1	AON PS229 (h53AON1) HPLC Chromatograph Pages 2, Exhibit Number 1140 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
2	AON PS229 (h53AON1) HPLC Method Report, Pages 3, Exhibit Number 1139 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
3	AON PS229 (h53AON1) Mass Spectrometry Data, Pages 3, Exhibit Number 1142 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
4	AON PS229 (h53AON1) Synthesis Laboratory Notebook Entry, Pages 1, Exhibit Number 1137 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
5	AON PS229L (h53AON229L) Certificate of Analysis, Pages 1, Exhibit Number 1129 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
6	AON PS43 (h51AON1) Certificate of Analysis, Pages 1, Exhibit Number 1134 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
7	AON PS43 (h51AON1) HPLC Chromatogram, Pages 1, Exhibit Number 1131 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
8	AON PS43 (h51AON1) HPLC Method Report, Pages 4, Exhibit Number 1130 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
9	AON PS43 (h51AON1) Mass Spectrometry Data, Pages 3, Exhibit Number 1135 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
10	AON PS43 (h51AON1) UPLC-UV Data, Pages 2, Exhibit Number 1136 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
11	AONs PS1958, PS1959, PS1960, PS1961, PS1962, PS1963, PS1964, PS1965, PS1966, and PS1967 HPLC Method Report, Pages 3, Exhibit Number 1143 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>

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12	Applicant-Initiated Interview Summary dated April 8, 2013 in U.S. Application Serial No. 13/094,548, (University of Western Australia Exhibit 2144, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-11).	<input type="checkbox"/>
13	Arechavala-Gomez V, et al., "Immunohistological intensity measurements as a tool to assess sarcolemma-associated protein expression," Neuropathol Appl Neurobiol 2010;36: 265-74.	<input type="checkbox"/>
14	ARECHAVALA-GOMEZA, V. et al., "Comparative Analysis of Antisense Oligonucleotide Sequences for Targeted Skipping of Exon 51 During Dystrophin Pre-mRNA Splicing in Human Muscle," Human Gene Therapy, Vol. 18:798-810 (2007)	<input type="checkbox"/>
15	ARORA, Vikram et al., "c-Myc Antisense Limits Rat Liver Regeneration and Indicates Role for c-Myc in Regulating Cytochrome P-450 3A Activity," The Journal of Pharmacology and Experimental Therapeutics, Vol. 292(3):921-928 (2000)	<input type="checkbox"/>
16	Asetek Danmark A/S v. CMI USA, Inc., 2014 WL 5990699, N.D. Cal. 2014, 8 pages, (Academisch Ziekenhuis Leiden Exhibit 1237, filed May 5, 2015 in Interference 106007 and 106008).	<input type="checkbox"/>
17	ASVADI, Parisa et al., "Expression and functional analysis of recombinant scFv and diabody fragments with specificity for human RhD," Journal of Molecular Recognition, Vol. 15:321-330 (2002)	<input type="checkbox"/>
18	Australian Application No. 2004903474, 36 pages, dated July 22, 2005 (Exhibit Number 1004 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
19	AVI BioPharma, Inc., "Exon 51 Sequence of Dystrophin," Document D19 as filed in Opposition of European Patent EP1619249, filed June 23, 2009, 7 pages	<input type="checkbox"/>
20	AZL's U.S. Patent Application No. 14/295,311 and claims, as-filed June 3, 2014 ("the '311 Application") (Exhibit Number 1077 filed in interferences 106008, 106007 on December 23, 2014)	<input type="checkbox"/>
21	Azofeifa J, et al., "X-chromosome methylation in manifesting and healthy carriers of dystrophinopathies: concordance of activation ratios among first degree female relatives and skewed inactivation as cause of the affected phenotypes," Hum Genet 1995;96:167-176.	<input type="checkbox"/>
22	BEAUCAGE, S.L. et al., "Deoxynucleoside Phosphoramidites - A New Class of Key Intermediates for Deoxypolynucleotide Synthesis," Tetrahedron Letters, Vol. 22(20):1859-1862 (1981)	<input type="checkbox"/>

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23	BELLARE, Priya et al., "A role for ubiquitin in the spliceosome assembly pathway," Nature Structural & Molecular Biology, Vol. 15(5):444-451 (2008) (Exhibit Number 1057 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
24	BELLARE, Priya et al., "Ubiquitin binding by a variant Jab1/MPN domain in the essential pre-mRNA splicing factor Prp8p," RNA, Vol. 12:292-302 (2006) (Exhibit Number 1056 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
25	BENNETT, C. Frank et al., "RNA Targeting Therapeutics: Molecular Mechanisms of Antisense Oligonucleotides as a Therapeutic Platform," Annu. Rev. Pharmacol. Toxicol., Vol. 50:259-293 (2010) (Exhibit Number 1025 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
26	BERGE, Stephen M. et al., "Pharmaceutical Salts," Journal of Pharmaceutical Sciences, Vol. 66(1):1-18 (1977)	<input type="checkbox"/>
27	Bestas et al., "Design and Application of Bispecific Splice Switching Oligonucleotides," Nuc. Acid Therap., Vol. 24, No. 1, pp. 13-24 (2014), Exhibit Number 1120 filed in interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
28	BRAASCH, Dwaine A. et al., "Locked nucleic acid (LNA): fine-tuning the recognition of DNA and RNA," Chemistry & Biology, Vol. 8:1-7 (2001) (Exhibit Number 2009 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
29	BRAASCH, Dwaine A. et al., "Novel Antisense and Peptide Nucleic Acid Strategies for Controlling Gene Expression," Biochemistry, Vol. 41(14):4503-4510 (2002) (Exhibit Number 2006 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
30	BREMMER-BOUT, Mattie et al., "Targeted Exon Skipping in Transgenic hDMD Mice: A Model for Direct Preclinical Screening of Human-Specific Antisense Oligonucleotides," Molecular Therapy, Vol. 10(2):232-240 (2004) (Exhibit Number 2024 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
31	Brooke MH, et al., "Clinical investigation in Duchenne dystrophy: 2. Determination of the "power" of therapeutic trials based on the natural history," Muscle Nerve. 1983;6:91-103.	<input type="checkbox"/>
32	BROWN, Susan C. et al., "Dystrophic phenotype induced in vitro by antibody blockade of muscle alpha-dystroglycan-laminin interaction," Journal of Cell Science, Vol. 112:209-216 (1999)	<input type="checkbox"/>
33	Bushby K, et al. "Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and pharmacological and psychosocial management," Lancet Neurol2010;9:77-93.	<input type="checkbox"/>

**INFORMATION DISCLOSURE
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Attorney Docket Number	AVN-013B

34	Bushby KM, et al., "The clinical, genetic and dystrophin characteristics of Becker muscular dystrophy," I. Natural history. J Neurol 1993;240:98-104.	<input type="checkbox"/>
35	Bushby KM, et al., "The clinical, genetic and dystrophin characteristics of Becker muscular dystrophy," II. Correlation of phenotype with genetic and protein abnormalities. J Neurol 1993;240: 105-112.	<input type="checkbox"/>
36	CANONICO, A.E. et al., "Expression of a CMV Promoter Drive Human alpha-1 Antitrypsin Gene in Cultured Lung Endothelial Cells and in the Lungs of Rabbits," Clinical Research, Vol. 39(2):219A (1991)	<input type="checkbox"/>
37	CIRAK, Sebahattin et al., "Exon skipping and dystrophin restoration in patients with Duchenne muscular dystrophy after systemic phosphorodiamidate morpholino oligomer treatment: an open-label, phase 2, dose-escalation study," Lancet, Vol. 378(9791):595-605 (2011)	<input type="checkbox"/>
38	Claim Chart 11/233,495, Pages 57, Exhibit Number 1216 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
39	Claim Chart 13/550,210, Pages 45, Exhibit Number 1217 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
40	Claim Chart, US 7,807,816, 14 pages (Exhibit Number 1063 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
41	Claim Chart, US 7,960,541, 17 pages (Exhibit Number 1064 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
42	Claim Chart, US 8,455,636, 32 pages (Exhibit Number 1062 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
43	Claim Comparison Chart - Claims 11 and 29 in 13/550,210, Pages 1, Exhibit Number 1226 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
44	Claim Comparison Chart 13/550,210 vs 11/233,495, Pages 12, Exhibit Number 1218 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>

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45	Claim Comparison Chart 13/550,210 vs 12/198,007, Pages 1, Exhibit Number 1219 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
46	Claims from US Application No. 11/233,495, 6 pages, dated September 21, 2005 (Exhibit Number 2068 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
47	Classification Excerpts from USPC System, 21 pages, (Academisch Ziekenhuis Leiden Exhibit 1234, filed May 5, 2015 in Interference 106007 and 106008).	<input type="checkbox"/>
48	COLLINS, C.A. et al., "Duchenne's muscular dystrophy: animal models used to investigate pathogenesis and develop therapeutic strategies," Int. J. Exp. Pathol., Vol. 84(4):165-172 (2003)	<input type="checkbox"/>
49	Confirmation of Dystrophin Exon 48 to 50 Deletion in Cell Line 8036 Laboratory Notebook Entry, Pages 3, Exhibit Number 1167 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
50	Confirmation of Dystrophin Exon 52 Deletion in Cell Line R1809 Laboratory; Notebook Entry, Pages 3, Exhibit Number 1168 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>

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1	Hoffman EP, et al., "Characterization of dystrophin in muscle-biopsy specimens from patients with Duchenne's or Becker's muscular dystrophy" N Engl J Med 1988;318:1363-68.	<input type="checkbox"/>
2	Hoffman EP, et al., "Restoring dystrophin expression in Duchenne muscular dystrophy muscle: Progress in exon skipping and stop codon read through," Am J Path 2011;179:12-22.	<input type="checkbox"/>
3	HUDZIAK, Robert M. et al., "Antiproliferative Effects of Steric Blocking Phosphorodiamidate Morpholino Antisense Agents Directed against c-myc," Antisense & Nucleic Acid Drug Development, Vol. 10:163-176 (2000) (Exhibit Number 1032 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
4	HUDZIAK, Robert M. et al., "Resistance of Morpholino Phosphorodiamidate Oligomers to Enzymatic Degradation," Antisense & Nucleic Acid Drug Development, Vol. 6:267-272 (1996)	<input type="checkbox"/>
5	HUSSEY, Nicole D. et al., "Analysis of five Duchenne muscular dystrophy exons and gender determination using conventional duplex polymerase chain reaction on single cells," Molecular Human Reproduction, Vol. 5(11):1089-1094 (1999)	<input type="checkbox"/>
6	Interim Guidance on Patent Subject Matter Eligibility ("the December Guidance," 16 pages, (Exhibit Number 2119 filed in interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
7	International Patent Application No. PCT/AU2000/00693 ("Wright"), published as WO 00/78341 on December 28, 2000, 201 pages, (Exhibit Number 2125 filed in interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
8	International Preliminary Report on Patentability and Written Opinion for Application No. PCT/US2009/061960, 8 pages, dated April 26, 2011	<input type="checkbox"/>
9	International Preliminary Report on Patentability for Application No. PCT/AU2005/000943, 8 pages, dated December 28, 2006	<input type="checkbox"/>
10	International Preliminary Report on Patentability, PCT/US2013/077216, dated June 23, 2015, pages 1-7.	<input type="checkbox"/>
11	International Preliminary Report on Patentability, PCT/US2014/029610, dated July1, 2015, pages 42.	<input type="checkbox"/>

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12	International Search Report and Written Opinion of the International Searching Authority issued in International Patent Application No. PCT/US2013/077216, 5 pages, dated March 27, 2014	<input type="checkbox"/>
13	International Search Report and Written Opinion of the International Searching Authority issued in International Patent Application No. PCT/US2014/029610, 6 pages, dated September 18, 2014	<input type="checkbox"/>
14	International Search Report and Written Opinion of the International Searching Authority issued in International Patent Application No. PCT/US2014/029689, 8 pages, dated October 21, 2014	<input type="checkbox"/>
15	International Search Report and Written Opinion of the International Searching Authority issued in International Patent Application No. PCT/US2014/029766, 8 pages, dated October 21, 2014	<input type="checkbox"/>
16	International Search Report for Application No. PCT/AU2005/000943, 5 pages, dated October 20, 2005	<input type="checkbox"/>
17	International Search Report for Application No. PCT/US01/14410, 5 pages, dated March 6, 2002	<input type="checkbox"/>
18	International Search Report for Application No. PCT/US2009/061960, 9 pages, dated April 6, 2010	<input type="checkbox"/>
19	Invitation to pay fees and Partial International Search Report issued by the International Search Authority in International Patent Application No. PCT/US2014/029689, 8 pages, dated July 29, 2014	<input type="checkbox"/>
20	ISIS Pharmaceuticals website, 2 pages, http://www.isispharm.com/Pipeline/Therapeutic-Areas/Other.htm (2014) (Exhibit Number 2021 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
21	IVERSEN, Patrick L. et al., "Efficacy of Antisense Morpholino Oligomer Targeted to c-myc in Prostate Cancer Xenograft Murine Model and a Phase I Safety Study in Humans," Clinical Cancer Research, Vol. 9:2510-2519 (2003)	<input type="checkbox"/>
22	JARVER, Peter et al., "A Chemical View of Oligonucleotides for Exon Skipping and Related Drug Applications," Nucleic Acid Therapeutics, Vol. 24(1):37-47 (2014) (Exhibit Number 2061 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>

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23	JASON, Tracey L.H. et al., "Toxicology of antisense therapeutics," Toxicology and Applied Pharmacology, Vol. 201:66-83 (2004) (Exhibit Number 2027 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
24	JEARAWIRIYAPASARN, Natee et al., "Long-term improvement in mdx cardiomyopathy after therapy with peptide-conjugated morpholino oligomers," Cardiovascular Research, Vol. 85:444-453 (2010)	<input type="checkbox"/>
25	JEARAWIRIYAPASARN, Natee et al., "Sustained Dystrophin Expression Induced by Peptide-conjugated Morpholino Oligomers in the Muscles of mdx Mice," Mol. Ther., Vol. 16(9):1624-1629 (2008)	<input type="checkbox"/>
26	Job Posting by Sarepta for "Scientist II, Muscle Biology" (2 pages), (Academisch Ziekenhuis Leiden Exhibit 1233, filed April 3, 2015 in Interference 106007 and 106008).	<input type="checkbox"/>
27	JONES, Simon S. et al., "The Protection of Uracil and Guanine Residues in Oligonucleotide Synthesis," Tetrahedron Letters, Vol. 22(47):4755-4758 (1981)	<input type="checkbox"/>
28	KARLEN, Yann et al., "Statistical significance of quantitative PCR," BMC Bioinformatics, 8:131, 16 pages (2007) (Exhibit Number 1033 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
29	KARRAS, James G. et al., "Deletion of Individual Exons and Induction of Soluble Murine Interleukin-5 Receptor-alpha Chain Expression through Antisense Oligonucleotide-Mediated Redirection of Pre-mRNA splicing," Molecular Pharmacology, Vol. 58:380-387 (2000)	<input type="checkbox"/>
30	KAYE, Ed, "Results of the Eteplirsen Phase 2b and Phase 2b Extension Study in Duchenne Muscular Dystrophy," 8th Annual Meeting of the Oligonucleotide Therapeutics Society, Session 9: Advances in Oligonucleotide Clinical Development II, Page 48 (2012)	<input type="checkbox"/>
31	KINALI, Maria et al., "Local restoration of dystrophin expression with the morpholino oligomer AVI-4658 in Duchenne muscular dystrophy: a single-blind, placebo-controlled, dose-escalation, proof-of-concept study," Lancet Neurol., Vol. 8:918-928 (2009)	<input type="checkbox"/>
32	King et al., "A Dictionary of Genetics," Oxford University Press, 4th Ed. (1990), Exhibit Number 1189 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
33	KOENIG, M. et al., "The Complete Sequence of Dystrophin Predicts a Rod-Shaped Cytoskeleton Protein," Cell, Vol. 53:219-228 (1988) (Exhibit Number 1010 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>

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34	KOENIG, M. et al., "The Molecular Basis for Duchenne versus Becker Muscular Dystrophy: Correlation of Severity with Type of Deletion," Am. J. Hum. Genet., Vol. 45:498-506 (1989) (Exhibit Number 1011 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
35	Kohler M, et al., "Quality of life, physical disability and respiratory impairment in Duchenne muscular dystrophy," Am J Respir Crit Care Med 2005;172:1032-6.	<input type="checkbox"/>
36	KOSHKIN, Alexei A. et al., "LNA (Locked Nucleic Acids): Synthesis of the Adenine, Cytosine, Guanine, 5-Methylcytosine, Thymine and Uracil Bicyclonucleoside Monomers, Oligomerisation, and Unprecedented Nucleic Acid Recognition," Tetrahedron, Vol. 54:3607-3630 (1998) (Exhibit Number 2007 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
37	Kurreck J., "Antisense Technologies: Improvement Through Novel Chemical Modifications", European Journal of Biochemistry, Vol.270(8):1628-1644 (2003)	<input type="checkbox"/>
38	Lab-on-a-Chip Data, Pages 28, Exhibit Number 1185 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
39	Laboratory Notebook Entry (Exon 51 Experiments): RT-PCR Analysis of 8036 Cells, Pages 2, Exhibit Number 1179 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
40	Laboratory Notebook Entry (Exon 51 Experiments): RT-PCR Analysis of KM155.C25 Cells, Pages 2, Exhibit Number 1178 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
41	Laboratory Notebook Entry (Exon 51 Experiments): Transfection of 8036 Cells, Pages 1, Exhibit Number 1172 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
42	Laboratory Notebook Entry (Exon 51 Experiments): Transfection of KM155.C25 Cells, Pages 1, Exhibit Number 1171 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
43	Laboratory Notebook Entry (Exon 53 Experiments): RT-PCR Analysis of KM155.C25 Cells, Pages 2, Exhibit Number 1180 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
44	Laboratory Notebook Entry (Exon 53 Experiments): RT-PCR Analysis of R1809 Cells, Pages 2, Exhibit Number 1181 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>

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45	Laboratory Notebook Entry (Exon 53 Experiments): Transfection of KM155.C25 Cells, Pages 1, Exhibit Number 1173 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
46	Laboratory Notebook Entry (Exon 53 Experiments): Transfection of R1809 Cells, Pages 1, Exhibit Number 1174 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
47	Laboratory Notebook Entry: General RNA recovery, 1 Page, Exhibit Number 1176 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
48	Laboratory Notebook Entry: Lab-on-a-Chip Analysis, Pages 3, Exhibit Number 1184 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
49	Larsen et al., "Antisense properties of peptide nucleic acid," Biochim. Et Biophys. Acta, Vol. 1489, pp. 159-166 (1999), Exhibit Number 1190 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
50	List of Publications for Matthew J. A. Wood, M.D., D. PHIL., 11 pages, (Exhibit Number 2124 filed in interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>

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1	Exon 53 Internal Sequence Schematic, Pages 1, Exhibit Number 1225 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
2	Fairclough et al., "Therapy for Duchenne muscular dystrophy: renewed optimism from genetic approaches," Nature Reviews, Vol. 14, pp. 373-378 (June, 2013), Exhibit Number 1112 filed in interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
3	FALL, Abbie M. et al., "Induction of revertant fibres in the mdx mouse using antisense oligonucleotides," Genetic Vaccines and Therapy, Vol. 4:3, doi:10.1186/1479-0556-4-3, 12 pages (2006)	<input type="checkbox"/>
4	Federal Register, Vol. 58, No. 183, pp. 49432-49434, September 23, 1993 (6 pages); [Cited as: 58 FR 49432-01, 1993 WL 371451 (F.R.)], Exhibit Number 1221 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
5	Federal Register, Vol. 69, No. 155, pp. 49960-50020 dated August 12, 2004 (62 pages), Exhibit Number 1220 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
6	File Excerpt from AZL U.S. Patent Application 11/233,495: Amendment After Non-Final Office Action, as-filed November 1, 2010 (Exhibit Number 1085 filed in interferences 106008, 106007 on December 23, 2014)	<input type="checkbox"/>
7	File Excerpt from AZL U.S. Patent Application 11/233,495: Claims examined in Non-Final Office Action, dated December 1, 2008 (Exhibit Number 1079 filed in interferences 106008, 106007 on December 23, 2014)	<input type="checkbox"/>
8	File Excerpt from AZL U.S. Patent Application 11/233,495: Final Office Action dated August 31, 2010 (Exhibit Number 1086 filed in interferences 106008, 106007 on December 23, 2014)	<input type="checkbox"/>
9	File Excerpt from U.S. Patent Application 11/233,495: Non-Final Office Action dated December 1, 2008 and Final Office Action dated June 25, 2009 (Exhibit Number 1078 filed in interferences 106008, 106007 on December 23, 2014)	<input type="checkbox"/>
10	File Excerpt from U.S. Patent Application No. 12/198,007: AZL's Preliminary Amendment and Response, as-filed November 7, 2008 (Exhibit Number 1075 filed in interferences 106008, 106007 on December 23, 2014)	<input type="checkbox"/>
11	File Excerpt from U.S. Patent Application No. 12/976,381: AZL's First Preliminary Amendment, as-filed December 22, 2010 (Exhibit Number 1076 filed in interferences 106008, 106007 on December 23, 2014)	<input type="checkbox"/>

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12	File Excerpts from Prosecution History of U.S. Patent Application No. 13/270,992 ("UWA's U.S. Patent 8,486,907"), Pages 122, Exhibit Number 1006 filed in Interference 106,013 on February 17, 2015.	<input type="checkbox"/>
13	File Excerpts from U.S. Patent Application No. 11/233,495: Response to Non- Final Office Action, as filed July 26, 2011 (14 pages), Exhibit Number 1222 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
14	File Excerpts from U.S. Patent Application No. 13/270,992 ("UWA's U.S. Patent 8,486,907"): NFOA, dated 7/30/2012; Applicant-Initiated Interview Summary, dated 11/8/2012; Amendment, as filed January 30, 2013; NOA, dated 4/4/2013, Exhibit Number 1118 (122 pages) filed in interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
15	Flanagan, Mitchell W., et al., "A cytosine analog that confers enhanced potency to antisense oligonucleotides," Proc. Nat'l Acad. Sci. USA, Vol. 96, pp. 3513-3518 (March, 1999), Exhibit Number 1211 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
16	FLANIGAN, Kevin M. et al., "Pharmacokinetics and safety of single doses of drisapersen in non-ambulant subjects with Duchenne muscular dystrophy: Results of a double-blind randomized clinical trial," Neuromuscular Disorders, Vol. 24:16-24 (2014) (Exhibit Number 2038 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
17	Flanigan, Kevin M., et al. (2003) "Rapid Direct Sequence Analysis of the Dystrophin Gene," Am. J. Hum. Genet. 72:931-939, dated February 17, 2015 (Exhibit Number 2120 filed in interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
18	Fletcher S., et al. "Morpholino oligomer-mediated exon skipping averts the onset of dystrophic pathology in the mdx mouse. Mol Ther 2007;15:1587-1592.	<input type="checkbox"/>
19	FLETCHER, Sue et al., "Dystrophin Isoform Induction In Vivo by Antisense-mediated Alternative Splicing," Molecular Therapy, Vol. 18(6):1218-1223 (2010)	<input type="checkbox"/>
20	FLETCHER, Sue et al., "Targeted Exon Skipping to Address 'Leaky' Mutations in the Dystrophin Gene," Molecular Therapy-Nucleic Acids, Vol. 1, e48, doi:10.1038/mtna.2012.40, 11 pages (2012)	<input type="checkbox"/>
21	FLETCHER, Susan et al., "Dystrophin expression in the mdx mouse after localised and systemic administration of a morpholino antisense oligonucleotide," J. Gene Med., Vol. 8:207-216 (2006)	<input type="checkbox"/>
22	FLETCHER, Susan et al., "Gene therapy and molecular approaches to the treatment of hereditary muscular disorders," Curr. Opin. Neurol., Vol. 13:553-560 (2000)	<input type="checkbox"/>

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23	FOSTER, Helen et al., "Genetic Therapeutic Approaches for Duchenne Muscular Dystrophy," Human Gene Therapy, Vol. 23:676-687 (2012)	<input type="checkbox"/>
24	Fourth Declaration of Erik Sontheimer, Ph.D. (Pursuant to Bd.R. 41.155(b)(2) and SO ¶¶ 155.1.3 and 155.1.4), dated March 9, 2015, (University of Western Australia Exhibit 2138, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-4).	<input type="checkbox"/>
25	FRAGALL, Clayton T. et al., "Mismatched single stranded antisense oligonucleotides can induce efficient dystrophin splice switching," BMC Medical Genetics, Vol. 12:141, 8 pages (2011) (Exhibit Number 2019 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
26	FRALEY, Robert et al., "New generation liposomes: the engineering of an efficient vehicle for intracellular delivery of nucleic acids," Trends Biochem., Vol. 6:77-80 (1981)	<input type="checkbox"/>
27	FRAZIER, Kendall S. et al., "Species-specific Inflammatory Responses as a Primary Component for the Development of Glomerular Lesions in Mice and Monkeys Following Chronic Administration of a Second-generation Antisense Oligonucleotide," Toxicologica Pathology, 13 pages (2013) (Exhibit No. 2040, filed in Interferences 106,007, 106,008, 106,013 on November 18, 2014.)	<input type="checkbox"/>
28	FRIEDMANN, Theodore, "Progress Toward Human Gene Therapy," Science, Vol. 244(4910):1275-1281 (1989)	<input type="checkbox"/>
29	GEBSKI, Bianca L. et al., "Morpholino antisense oligonucleotide induced dystrophin exon 23 skipping in mdx mouse muscle," Human Molecular Genetics, Vol. 12(15):1801-1811 (2003)	<input type="checkbox"/>
30	Generic Method for Average Mass Determination Using LC-UV-MS in the Negative Mode, Pages 15, Exhibit Number 1145 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
31	Generic UPLC Purity Method for Oligonucleotides (19- to 25-mers), Pages 18, Exhibit Number 1156 filed in Interferences 106,007 and 106,008 on February 16, 2015.	<input type="checkbox"/>
32	GENNARO, Alfonso R., (ed.), Remington's Pharmaceutical Sciences, 18th Edition, Mack Publishing, Co., Easton PA, 2020 pages (1990)	<input type="checkbox"/>
33	GILES, Richard V. et al., "Antisense Morpholino Oligonucleotide Analog Induces Missplicing of C-myc mRNA," Antisense & Nucleic Acid Drug Development, Vol. 9:213-220 (1999)	<input type="checkbox"/>

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34	GlaxoSmithKline Press Release, Issued in London, UK, dated June 27, 2013 (5 pages), Exhibit Number 1202 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
35	GlaxoSmithKline, "GSK and Prosensa announce start of Phase III study of investigational Duchenne Muscular Dystrophy medication," press release, 6 pages, dated January 19, 2011 (Exhibit Number 2060 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
36	GlaxoSmithKline, "Prosensa regains rights to drisapersen from GSK and retains rights to all other programmes for the treatment of Duchenne muscular dystrophy (DMD), press release, 4 pages, dated January 13, 2014 (Exhibit 2040 in Interferences 106007, 106008, and 106013 on November 18, 2014).	<input type="checkbox"/>
37	GOEMANS, Nathalie M. et al., "Systemic Administration of PRO051 in Duchenne's Muscular Dystrophy," The New England Journal of Medicine, Vol. 364:1513-1522 (2011) (Exhibit Number 2036 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
38	Gordon, Peter M. et al. "Kinetic Characterization of the Second Step of Group II Intron Splicing: Role of Metal Ions and the Cleavage Site 2'-OH in Catalysis," Biochemistry, Vol. 39, pp. 12939-12952 (2000), Exhibit Number 1188 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
39	GORDON, Peter M. et al., "Metal ion catalysis during the exon-ligation step of nuclear pre-mRNA splicing: Extending the parallels between the spliceosome and group II introns," RNA, Vol. 6:199-205 (2000) (Exhibit Number 1055 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
40	GOYENVALLE, Aurelie et al., "Prevention of Dystrophic Pathology in Severely Affected Dystrophin/Utrophin-deficient Mice by Morpholino-oligomer-mediated Exon-skipping," Molecular Therapy, Vol. 18(1):198-205 (2010)	<input type="checkbox"/>
41	Hammond Suzan M. et al., "PRO-051, an antisense oligonucleotide for the potential treatment of Duchenne muscular dystrophy," Curr. Opinion Mol. Therap., Vol. 12, No. 4, pp. 478-486 (2010), Exhibit Number 1121 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
42	Hammond, Suzan M. et al., "Genetic therapies for RNA mis-splicing diseases," Cell, Vol.27, No. 5, pp. 196-205 (May, 2011), Exhibit Number 1113 filed in interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
43	HAMMOND, Suzan M. et al., "Correlating In Vitro Splice Switching Activity With Systemic In Vivo Delivery Using Novel ZEN-modified Oligonucleotides," Molecular Therapy - Nucleic Acids, Vol. 3:1, 11 pages (2014) (Exhibit Number 2011 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
44	HARDING, PL et al., "The Influence of Antisense Oligonucleotide Length on Dystrophin Exon Skipping," Molecular Therapy, Vol. 15(1):157-166 (2007) (Exhibit Number 1030 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>

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45	HAREL-BELLAN, Annick et al., "Specific Inhibition of c-myc Protein Biosynthesis Using an Antisense Synthetic Deoxy-Oligonucleotide in Human T Lymphocytes," The Journal of Immunology, Vol. 140(7):2431-2435 (1988)	<input type="checkbox"/>
46	Havenga, M.J.E., et al., "Exploiting the Natural Diversity in Adenovirus Tropism for Therapy and Prevention of Disease," J. Virol., Vol. 76, No. 9, pp. 4612-4620 (May, 2002), Exhibit Number 1123 filed in interferences 106,007 and 106,008 on February 13, 2015.	<input type="checkbox"/>
47	HEASMAN, Janet, "Morpholino Oligos: Making Sense of Antisense?" Developmental Biology, Vol. 243:209-214 (2002)	<input type="checkbox"/>
48	HEEMSKERK, Hans A. et al., "In vivo comparison of 2'-O-methyl phosphorothioate and morpholino antisense oligonucleotides for Duchenne muscular dystrophy exon skipping," The Journal of Gene Medicine, Vol. 11:257-266 (2009) (Exhibit Number 2020 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
49	HEID, Christian A. et al., "Real Time Quantitative PCR," Genome Research, Vol. 6:986-994 (1996) (Exhibit Number 1061 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
50	HERSCHLAG, Daniel et al., "Contributions of 2'-Hydroxyl Groups of the RNA Substrate to Binding and Catalysis by the Tetrahymena Ribozyme: An Energetic Picture of an Active Site Composed of RNA," Biochemistry, Vol. 32:8299-8311 (1993) (Exhibit Number 1031 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>

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1	US Transmittal, application as-filed, and Preliminary Amendment for Application No. 13/270,992, 101 pages, dated October 11, 2011 (Exhibit Number 2098 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
2	US Transmittal, application as-filed, and Preliminary Amendment for Application No. 13/271,080, 115 pages, dated October 11, 2011 (Exhibit Number 2111 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
3	US Updated Filing Receipt for Application No. 13/550,210, 3 pages, dated December 11, 2012 (Exhibit Number 2044 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
4	USPTO "2014 Procedure for Subject Matter Eligibility Analysis of Claims Reciting or Involving...Natural Products" ("the March Guidance"), 19 pages, (Exhibit Number 2118 filed in interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
5	USPTO Written Description Training Materials, Revised March 25, 2008, Example 12, 6 pages, (Exhibit Number 1068 filed in interferences 106008, 106007 on December 23, 2014)	<input type="checkbox"/>
6	UWA Clean Copy of Claims and Sequence, as filed in Interference No. 106,007 on August 1, 2014 (Paper 12), 8 pages, (Exhibit Number 2126 filed in interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
7	UWA Clean Copy of Claims and Sequence, as filed in Interference No. 106,007 on August 7, 2014 (Paper 12), 8 pages, (Exhibit Number 2127 filed in interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
8	UWA Motion 1 (For Judgment Under 35 § 112(a)) from Int. No. 106,007 (PN210), 40 Pages, Exhibit Number 1005 filed in Interference 106,013 on February 17, 2015.	<input type="checkbox"/>
9	UWA Motion 1 (For Judgment Under 35 § 112(a)) from Int. No. 106,008 (Doc 213), 38 Pages, Exhibit Number 1004 filed in Interference 106,013 on February 17, 2015.	<input type="checkbox"/>
10	UWA submission of teleconference transcript, 28 pages, dated December 12, 2014 (Exhibit Number 2114 filed in interferences 106008 and 106007 on December 12, 2014)	<input type="checkbox"/>
11	Valorization Memorandum published by the Dutch Federation of University Medical Centers in March 2009, (University of Western Australia Exhibit 2140, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-33).	<input type="checkbox"/>

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12	VAN DEUTEKOM et al., "Antisense-induced exon skipping restores dystrophin expression in DMD patient derived muscle cells," HUMAN MOLECULAR GENETICS Vol. 10, No. 15: 1547-1554 (2001) (Exhibit Number 1084 filed in interferences 106008, 106007 on December 23, 2014)	<input type="checkbox"/>
13	VAN DEUTEKOM et al., "Local Dystrophin Restoration with Antisense Oligonucleotide PRO051," N. Engl. J. Med., Vol. 357, No. 26, pp. 2677-2686 (December, 2007), Exhibit Number 1213 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
14	VAN DEUTEKOM, Judith C.T. et al., "Advances in Duchenne Muscular Dystrophy Gene Therapy," Nature Reviews Genetics, Vol. 4(10):774-783 (2003)	<input type="checkbox"/>
15	Van Ommen 2002 PCT (WO 02/24906 A1) 43 pages, (Exhibit Number 1071 filed in interferences 106008, 106007 on December 23, 2014)	<input type="checkbox"/>
16	van Putten M. et al., "The Effects of Low Levels of Dystrophin on Mouse Muscle Function and Pathology. PLoS ONE 2012;7:e31937, 13 pages	<input type="checkbox"/>
17	Van Vliet, Laura et al., "Assessment of the Feasibility of Exon 45-55 Multiexon Skipping for Duchenne Muscular Dystrophy", BMC Medical Genetics, Vol.9(1):105 (2008)	<input type="checkbox"/>
18	VERMA, Sandeep et al., "Modified Oligonucleotides: Synthesis and Strategy for Users," Annu. Rev. Biochem., Vol. 67:99-134 (1998) (Exhibit Number 1040 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
19	VOIT, Thomas et al., "Safety and efficacy of drisapersen for the treatment of Duchenne muscular dystrophy (DEMAND II): an exploratory, randomised, placebo-controlled phase 2 study," Lancet Neurol., Vol. 13:987-996 (2014) (Exhibit Number 2037 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
20	VOLLOCH, Vladimir et al., "Inhibition of Pre-mRNA Splicing by Antisense RNA in Vitro: Effect of RNA Containing Sequences Complementary to Exons," Biochemical and Biophysical Research Communications, Vol. 179 (3):1593-1599 (1991)	<input type="checkbox"/>
21	Wahlestedt et al., "Potent and nontoxic antisense oligonucleotides containing locked nucleic acids," PNAS, Vol. 97, No. 10, pp. 5633-5638 (May, 2000), Exhibit Number 1201 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
22	Wang et al., "In Vitro evaluation of novel antisense oligonucleotides is predictive of in vivo exon skipping activity for Duchenne muscular dystrophy," J. Gene Medicine, Vol. 12, pp. 354-364 (March, 2010), Exhibit Number 1115 filed in interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>

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23	WANG, Chen-Yen et al., "pH-sensitive immunoliposomes mediate target-cell-specific delivery and controlled expression of a foreign gene in mouse," Proc. Natl. Acad. Sci. USA, Vol. 84:7851-7855 (1987)	<input type="checkbox"/>
24	WATAKABE, Akiya et al., "The role of exon sequences in splice site selection," Genes & Development, Vol. 7:407-418 (1993)	<input type="checkbox"/>
25	Watanabe et al., "Plasma Protein Binding of an Antisense Oligonucleotide Targeting Human ICAM-1 (ISIS 2302)," Oligonucleotides, Vol. 16, pp. 169- 180 (2006), Exhibit Number 1197 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
26	WIJNAENDTS, L.C.D. et al., "Prognostic importance of DNA flow cytometric variables in rhabdomyosarcomas," J. Clin. Pathol., Vol. 46:948-952 (1993) (Exhibit Number 1041 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
27	Wilton et al. (2007) "Antisense Oligonucleotide-induced Exon Skipping Across the Human Dystrophin Gene Transcript," Molecular Therapy 15(7):1288-1296, 10 pages, (Exhibit Number 2121 filed in interferences 106,007 and 106,008 on February 17, 2015	<input type="checkbox"/>
28	WILTON, Stephen D. et al., "Antisense oligonucleotides in the treatment of Duchenne muscular dystrophy: where are we now?" Neuromuscular Disorders, Vol. 15:399-402 (2005)	<input type="checkbox"/>
29	WILTON, Stephen D. et al., "Specific removal of the nonsense mutation from the mdx dystrophin mRNA using antisense oligonucleotides," Neuromuscular Disorders, Vol. 9:330-338 (1999)	<input type="checkbox"/>
30	WO 2002/24906 A1 of AZL, (University of Western Australia Exhibit 2134, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-43.)	<input type="checkbox"/>
31	WO 2004/083432 (the published AZL PCT Application, "Van Ommen"), Pages 71, Exhibit Number 1003 filed in Interference 106,013 on February 17, 2015.	<input type="checkbox"/>
32	WO 2013/112053 A1, (University of Western Australia Exhibit 2130, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-177).	<input type="checkbox"/>
33	WOLFF, Jon A. et al., "Direct Gene Transfer into Mouse Muscle in Vivo," Science, Vol. 247:1465-1468 (1990)	<input type="checkbox"/>

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34	WONG, Marisa L. et al., "Real-time PCR for mRNA quantitation," BioTechniques, Vol. 39:75-85 (2005) (Exhibit Number 1066 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
35	Wood, "Toward an Oligonucleotide Therapy for Duchenne Muscular Dystrophy: A Complex Development Challenge," Science Translational Medicine, Vol. 2, No. 25, pp. 1-6 (March, 2010), Exhibit Number 1116 filed in interferences 106,007 and 106,008 on February 17, 2015, Doc 335.	<input type="checkbox"/>
36	Written Opinion for Application No. PCT/AU2010/001520, 6 pages, dated January 21, 2011	<input type="checkbox"/>
37	WU, B. et al., "Dose-dependent restoration of dystrophin expression in cardiac muscle of dystrophic mice by systemically delivered morpholino," Gene Therapy, Vol. 17:132-140 (2010)	<input type="checkbox"/>
38	WU, Bo et al., "Effective rescue of dystrophin improves cardiac function in dystrophin-deficient mice by a modified morpholino oligomer," PNAS, Vol. 105(39):14814-14819 (2008)	<input type="checkbox"/>
39	WU, Bo et al., "Targeted Skipping of Human Dystrophin Exons in Transgenic Mouse Model Systemically for Antisense Drug Development," PLoS One, Vol. 6(5):e19906, 11 pages (2011)	<input type="checkbox"/>
40	WU, George Y. et al., "Receptor-mediated Gene Delivery and Expression in Vivo," The Journal of Biological Chemistry, Vol. 263(29):14621-14624 (1988)	<input type="checkbox"/>
41	WU, George Y. et al., "Receptor-mediated in Vitro Gene Transformation by a Soluble DNA Carrier System," The Journal of Biological Chemistry, Vol. 262(10):4429-4432 (1987)	<input type="checkbox"/>
42	Wyatt et al. "Site-specific cross-linking of mammalian U5 snRNP to the 5' splice site before the first step of pre-mRNA splicing," Genes & Development, Vol. 6, pp. 2542-2553 (1992), Exhibit Number 1198 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
43	Yin et al., "A fusion peptide directs enhanced systemic dystrophin exon skipping and functional restoration in dystrophin-deficient mdx mice," Human Mol. Gen., Vol. 18, No. 22, pp. 4405-4414 (2009), Exhibit Number 1200 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
44	Yin et al., "Cell Penetrating peptide-conjugated antisense oligonucleotides restore systemic muscle and cardiac dystrophin expression and function," Human Mol. Gen., Vol. 17, No. 24, pp. 3909-3918 (2008), Exhibit Number 1199 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>

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45	Yin et al., "Functional Rescue of Dystrophin-deficient mdx Mice by a Chimeric Peptide-PMO," Mol. Therapy, Vol. 18, No. 10, pp. 1822-1829 (October, 2010), Exhibit Number 1117 filed in interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
46	Yokota et al., "Efficacy of Systematic Morpholino Exon-Skipping in Duchenne Dystrophy Dogs," American Neurological Assoc., Vol. 65, No. 6, pp. 667-676 (June, 2009), Exhibit Number 1214 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
47	Zoltek Corp. v. U.S., 95 Fed. Cl. 681 (2011), 23 pages, (Academisch Ziekenhuis Leiden Exhibit 1236, filed May 5, 2015 in Interference 106007 and 106008).	<input type="checkbox"/>
48	Sarepta, "AVI BioPharma Initiates Dosing in Phase 2 Study of Eteplirsen in Duchenne Muscular Dystrophy Patients," press release, 4 pages, dated August 15, 2011 (Exhibit Number 2082 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
49	Sarepta Therapeutics Press Release, dated January 12, 2015, Exhibit Number 1119 filed in interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
50	AZL's PCT/NL03/00214 (the as-filed AZL PCT Application) Exhibit No. 1006, filed in Interference No. 106,007, 64 pages, December 23, 2014	<input type="checkbox"/>

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	14214480
Filing Date	2014-03-14
First Named Inventor	Richard K. BESTWICK
Art Unit	1674
Examiner Name	D. H. Shin
Attorney Docket Number	AVN-013B

1	Confirmatory Study of Eteplirsen in DMD Patients, An Open-Label, Multi-Center, 48-Week Study With a Concurrent Untreated Control Arm to Evaluate the Efficacy and Safety of Eteplirsen in Duchenne Muscular Dystrophy ,Clinical Trials.gov, Clinical Trial Identifier NCT02255552, October 1, 2014, 3 pages	<input type="checkbox"/>
2	Confirmatory Study of Eteplirsen in DMD Patients, An Open-Label, Multi-Center, 48-Week Study With a Concurrent Untreated Control Arm to Evaluate the Efficacy and Safety of Eteplirsen in Duchenne Muscular Dystrophy, Clinical Trials.gov, Clinical Trial Identifier NCT02255552, May 26, 2015, 3 pages.	<input type="checkbox"/>
3	Coolidge v. Efendic, 2008 WL 2080735, Int. No. 105,457 (BPAI May 16, 2008), 42 pages, (Academisch Ziekenhuis Leiden Exhibit 1235, filed May 5, 2015 in Interference 106007 and 106008).	<input type="checkbox"/>
4	COREY, David R. et al., "Morpholino antisense oligonucleotides: tools for investigating vertebrate development," Genome Biology, Vol. 2(5):1015.1 - 1015.3 (2001) (Exhibit Number 1026 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
5	Corrected Priority Statement filed by UWA in Int. No. 106,008 (as PN 219),Pages 5, Exhibit Number 1002 filed in Interference 106,013 on February 17, 2015.	<input type="checkbox"/>
6	Cortes, Jesus J. et al., "Mutations in the conserved loop of human U5 snRNA generate use of novel cryptic 5' splice sites in vivo," EMBO J., Vol. 12, No. 13, pp. 5181-5189 (1993), Exhibit Number 1187 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
7	CROOKE, Stanley T., Antisense Drug Technology, Principles, Strategies, and Applications, Marcel Dekker, Inc., New York, Chapters 15 and 16, pages 375-389, 391-469 (2001) (Exhibit Number 2075 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
8	Curriculum Vitae of Judith van Deutekom, Pages 6, Exhibit Number 1126 filed in interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
9	Curriculum Vitae, Erik Joseph Sontheimer, 18 pages, dated September 29, 2014 (Exhibit Number 1013 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
10	CV, Professor Matthew J.A. Wood, 3 pages (Exhibit Number 2003 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
11	DAVIS, Richard J. et al., "Fusion of PAX7 to FKHR by the Variant t(1;13)(p36;q14) Translocation in Alveolar Rhabdomyosarcoma," Cancer Research, Vol. 54:2869-2872 (1994) (Exhibit Number 1027 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>

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Attorney Docket Number	AVN-013B

12	DE ANGELIS, Fernanda Gabriella et al., "Chimeric snRNA molecules carrying antisense sequences against the splice junctions of exon 51 of the dystrophic pre-mRNA induce exon skipping and restoration of a dystrophin synthesis in 48-50 DMD cells," PNAS, Vol. 99(14):9456-9461 (2002)	<input type="checkbox"/>
13	Decision on Appeal, Ex Parte Martin Gleave and Hideaki Miyake, Appeal No. 2005-2447, Appl. No. 09/619,908 (January 31, 2006) (2009 WL 6927761 (Bd.Pat.App.& Interf.), Pages 12, Exhibit Number 1207 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
14	Decision on Request for ReHearing, Ex Parte Roderick John Scott, Appeal No. 2008-004077, Appl. No. 10/058,825 (January 6, 2010) (2010 WL 191079 (Bd.Pat.App. & Interf.),Pages 21, Exhibit Number 1208 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
15	Declaration of Judith C.T. van Deutekom Under 37 C.F.R. §1.132, filed on January 27, 2012, in U.S. Patent Reexamination Control No 90/011,320, regarding U.S. Patent No. 7,534,879, (University of Western Australia Exhibit 2133, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-10).	<input type="checkbox"/>
16	Declaration of Judith van Deutekom, Pages 45, Exhibit Number 1125 filed in interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
17	DELLORUSSO, Christiana et al., "Functional correction of adult mdx mouse muscle using gutted adenoviral vectors expressing full-length dystrophin," PNAS, Vol. 99(20):12979-12984 (2002)	<input type="checkbox"/>
18	Deposition Transcript of Erik J. Sontheimer, Ph.D. of January 21, 2015 (99 pages), Exhibit Number 1215 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
19	Deposition Transcript of Matthew J. A. Wood, M.D. , D. Phil., January 22, 2015, including Errata Sheet, Pages 198, Exhibit Number 1007 filed in Interference 106,013 on February 17, 2015.	<input type="checkbox"/>
20	Deposition Transcript of Matthew J. A. Wood, M.D., D. Phil., Pages 196, Exhibit Number 1122 filed in interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
21	Desalting of Oligonucleotides, Pages 2, Exhibit Number 1132 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
22	DIRKSEN, Wessel P. et al., "Mapping the SF2/ASF Binding Sites in the Bovine Growth Hormone Exonic Splicing Enhancer," The Journal of Biological Chemistry, Vol. 275(37):29170-29177 (2000)	<input type="checkbox"/>

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Filing Date	2014-03-14
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Examiner Name	D. H. Shin
Attorney Docket Number	AVN-013B

23	DOMINSKI, Zbigniew et al., "Identification and Characterization by Antisense Oligonucleotides of Exon and Intron Sequences Required for Splicing," Molecular and Cellular Biology, Vol. 14(11):7445-7454 (1994)	<input type="checkbox"/>
24	DOMINSKI, Zbigniew et al., "Restoration of correct splicing in thalassemic pre-mRNA by antisense oligonucleotides," Proc. Natl. Acad. Sci. USA, Vol. 90:8673-8677 (1993)	<input type="checkbox"/>
25	DORAN, Philip et al., "Proteomic profiling of antisense-induced exon skipping reveals reversal of pathobiochemical abnormalities in dystrophic mdx diaphragm," Proteomics, Vol. 9:671-685, DOI 10.1002/pmic.200800441 (2009)	<input type="checkbox"/>
26	DOUGLAS, Andrew G.L. et al., "Splicing therapy for neuromuscular disease," Molecular and Cellular Neuroscience, Vol. 56:169-185 (2013) (Exhibit Number 2005 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
27	Doyle, Donald F., et al. (2001) "Inhibition of Gene Expression Inside Cells by PeptideNucleic Acids: Effect of mRNA Target Sequence, Mismatched Bases, and PNA Length," Biochemistry 40:53-64, Exhibit Number 2123 filed in interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
28	Dr. Wood Errata Sheet - 22 Jan 2015, Pages 2, Exhibit Number 1227 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
29	DUNCKLEY, Matthew G. et al., "Modification of splicing in the dystrophin gene in cultured Mdx muscle cells by antisense oligoribonucleotides," Human Molecular Genetics, Vol. 5(1):1083-1090 (1995)	<input type="checkbox"/>
30	DUNCKLEY, Matthew G. et al., "Modulation of Splicing in the DMD Gene by Antisense Oligoribonucleotides," Nucleosides & Nucleotides, Vol. 16(7-9):1665-1668 (1997)	<input type="checkbox"/>
31	ECKSTEIN, F., "Nucleoside Phosphorothioates," Ann. Rev. Biochem., Vol. 54:367-402 (1985) (Exhibit Number 1028 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
32	ELAYADI, Anissa N. et al., "Application of PNA and LNA oligomers to chemotherapy," Current Opinion in Investigational Drugs, Vol. 2(4):558-561 (2001)	<input type="checkbox"/>
33	Email from Danny Huntington to Interference Trial Section, dated September 21, 2014, Pages 2, Exhibit Number 3001 filed in Interference 106,007, 106,008, and 106,013 on September 26, 2014.	<input type="checkbox"/>

**INFORMATION DISCLOSURE
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Application Number	14214480
Filing Date	2014-03-14
First Named Inventor	Richard K. BESTWICK
Art Unit	1674
Examiner Name	D. H. Shin
Attorney Docket Number	AVN-013B

34	Email From Sharon Crane to Interference Trial Section, dated November 13, 2014, Pages 2, Exhibit Number 3002 filed in Interference 106,007, 106,008, and 106,013 on dated November 14, 2014.	<input type="checkbox"/>
35	Emery, A.E. H., "Population frequencies of inherited neuromuscular diseases - a world survey," Neuromuscul Disord 1991;1:19-29.	<input type="checkbox"/>
36	Errata sheet for the January 22, 2015 deposition of Matthew J. A. Wood, M.D., D. PHIL., 2 pages, (Exhibit Number 2128 filed in interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>
37	Errata sheet for the March 12, 2015 deposition of Erik J. Sontheimer, Ph.D., (University of Western Australia Exhibit 2149, filed April 3, 2015 in Interferences 106007, 106008, and 106013, page 1).	<input type="checkbox"/>
38	ERRINGTON, Stephen J. et al., "Target selection for antisense oligonucleotide induced exon skipping in the dystrophin gene," The Journal of Gene Medicine, Vol. 5:518-527 (2003)	<input type="checkbox"/>
39	European Office Action for Application No. 09752572.9, 5 pages, dated February 29, 2012	<input type="checkbox"/>
40	European Response, Application No. 10004274.6, 7 pages, dated November 5, 2013 (Exhibit Number 1060 filed in interferences 106008, 106007 on November 18, 2014)	<input type="checkbox"/>
41	European Response, Application No. 12198517.0, 7 pages, dated October 21, 2014 (Exhibit Number 2084 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
42	European Response, Application No. 13160338.3, 4 pages, dated June 26, 2014 (Exhibit Number 2085 filed in interferences 106008, 106013, 106007 on November 18, 2014)	<input type="checkbox"/>
43	European Search Report for Application No. 10004274.6, 12 pages, dated January 2, 2013	<input type="checkbox"/>
44	European Search Report for Application No. 12162995.0, 11 pages, dated January 15, 2013	<input type="checkbox"/>

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Filing Date	2014-03-14
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Art Unit	1674
Examiner Name	D. H. Shin
Attorney Docket Number	AVN-013B

45	European Search Report, EP15168694.6, dated July 23, 2015, pages 1-8.	<input type="checkbox"/>
46	Excerpts from Prosecution History of Application No. 13/741,150: Notice of Allowance dated March 16, 2015; List of References cited by Applicant and Considered by Examiner; Notice of Allowance and Fees due dated September 18, 2014; Amendment in Response to Non-Final Office Action dated July 11, 2014, (Academisch Ziekenhuis Leiden Exhibit 1229, filed April 3, 2015 in Interference 106007 and 106008, pages 1-133).	<input type="checkbox"/>
47	Excerpts from Prosecution History of Application No. 13/826,880: Notice of Allowance dated January 26, 2015 and Amendment in Response to Non-Final Office Action dated October 15, 2014, (Academisch Ziekenhuis Leiden Exhibit 1228, filed April 3, 2015 in Interference 106007 and 106008, pages 1-16).	<input type="checkbox"/>
48	Excerpts from Yeo (Ed.), "Systems Biology of RNA Binding Proteins," Adv. Exp. Med. Biol., Chapter 9, 56 pages (2014), (Academisch Ziekenhuis Leiden Exhibit 1232, filed April 3, 2015 in Interference 106007 and 106008, pages 1-56).	<input type="checkbox"/>
49	Excerpts of SEC Form 8-K, dated November 23 2014, for BioMarin Pharmaceutical Inc., (University of Western Australia Exhibit 2129, filed April 3, 2015 in Interferences 106007, 106008, and 106013, pages 1-9).	<input type="checkbox"/>
50	Exon 51 Internal Sequence Schematic, Pages 1, Exhibit Number 1224 filed in Interferences 106,007 and 106,008 on February 17, 2015.	<input type="checkbox"/>

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EXAMINER SIGNATURE

Examiner Signature	/Dana Shin/	Date Considered	10/14/2015
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/214,480	03/14/2014	Richard K. Bestwick	AVN-013B	3826

123147 7590 04/17/2015
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

EXAMINER

SHIN, DANA H

ART UNIT	PAPER NUMBER
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1674

NOTIFICATION DATE	DELIVERY MODE
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04/17/2015

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

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ipqualityassuranceboston@nelsonmullins.com

Application No.
14/214,480
#: 58401Applicant(s)
BESTWICK ET AL.**Office Action Summary**Examiner
DANA SHINArt Unit
1674AIA (First Inventor to File)
Status
No**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3-19-2015.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 16 and 21-33 is/are pending in the application.
 5a) Of the above claim(s) 28-33 is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 16 and 21-27 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 3-14-2014 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
 Paper No(s)/Mail Date ____.
- 3) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. ____.
- 4) ☐ Other: ____.

Application/Control Number: 14/214,480
Art Unit: 1674

Page 2

DETAILED ACTION

The present application is being examined under the pre-AIA first to invent provisions.

Election/Restrictions

Applicant's election without traverse of SEQ ID NO:5 in the reply filed on March 19, 2015 is acknowledged.

Status of Claims

Claims 16 and 21-33 are pending in the instant application.

Since it is found that SEQ ID NOs:4 and 6 overlap with applicant's elected SEQ ID NO:5, the restriction requirement among claims drawn to SEQ ID NOs:4-6 is withdrawn. Hence, claims 28-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected species, there being no allowable generic or linking claim. Accordingly, claims 16 and 21-27 are under examination on the merits in the instant case.

Information Disclosure Statement

The information disclosure statements submitted on March 19, 2015 have been considered by the examiner, except the information pertaining to AU 2003284638 A1 since applicant did not submit a legible copy of the reference. Note that applicant merely submitted the cover page only. Further, JP2008507577 is not considered because the entire reference is in non-English language. In addition, all non-English language foreign patent documents are considered only insofar as the English title and abstract.

Application/Control Number: 14/214,480
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Page 3

Claim Rejections - 35 USC § 112

The following is a quotation of 35 U.S.C. 112(b):

(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16, 22, 24, and 26 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

The claims recite each of “H44A(-8+15)”, “H44A(-7+15)”, and “H44A(-6+15)” following an oligonucleotide structure. The claims fail to particularly point out and distinctly claim how the names are associated with the claimed structures.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of pre-AIA 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

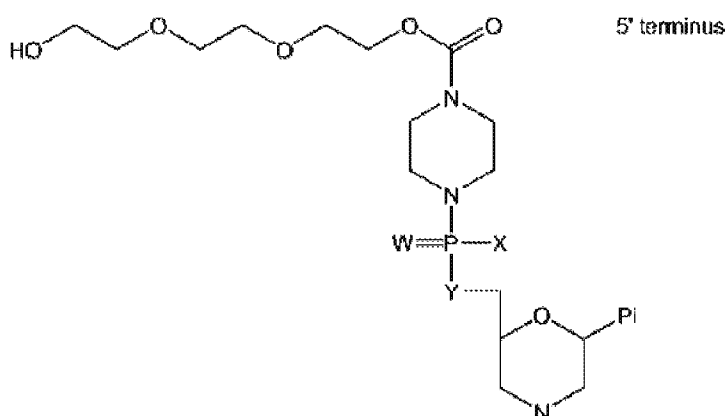
Application/Control Number: 14/214,480
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Page 4

Claims 21, 23, 25, and 27 are rejected under pre-AIA 35 U.S.C. 102(a) and 102(e) as being anticipated by Hanson (US 2012/0289457 A1).

Note that the transitional term “comprising” in claims 21, 23, 25, and 27 is open-ended and does not exclude any unrecited elements even in major amounts. See MPEP §2111.03.

Hanson discloses the 5' terminus of structure of a morpholino antisense oligonucleotide in Figure 1C as below:



Hanson also discloses SEQ ID NO:22 as an exemplary oligonucleotide sequence having the 5' terminus, wherein SEQ ID NO:22 comprises the nucleotide sequences of the structures claimed in claims 21, 23, 25, and 27. See Table 1 at page 25.

Hanson teaches making a composition comprising the oligonucleotide and a pharmaceutically acceptable carrier. See claim 59.

Accordingly, all claim limitations of claims 21, 23, 25, and 27 are taught by Hanson.

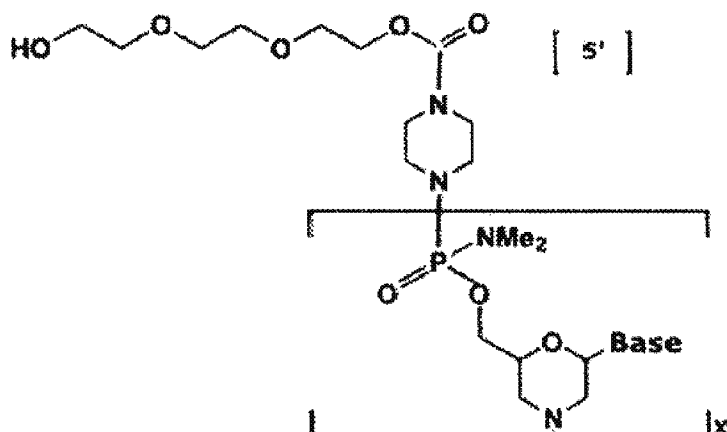
Claims 21, 23, 25, and 27 are rejected under pre-AIA 35 U.S.C. 102(a) and 102(e) as being anticipated by Hanson et al. (US 2012/0065169 A1).

Note that the transitional term “comprising” in claims 21, 23, 25, and 27 is open-ended and does not exclude any unrecited elements even in major amounts. See MPEP §2111.03.

Application/Control Number: 14/214,480
Art Unit: 1674

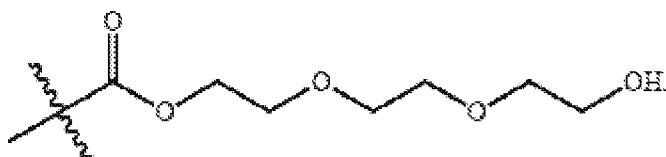
Page 5

Hanson et al. disclose the 5' terminus of structure of a morpholino antisense oligonucleotide in Figure 1B as below:



See also claim 29 as below:

29. The oligomer of claim 25, wherein R¹⁹ is piperizinyl or



Hanson et al. also disclose SEQ ID NO:22 as an exemplary oligonucleotide sequence having the 5' terminus, wherein SEQ ID NO:22 comprises the nucleotide sequences of the structures claimed in claims 21, 23, 25, and 27. See Table 11 at page 64.

Hanson et al. teach making a composition comprising the oligonucleotide and a pharmaceutically acceptable carrier. See paragraph 0305.

Accordingly, all claim limitations of claims 21, 23, 25, and 27 are taught by Hanson et al.

Claim Rejections - 35 USC § 103

The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Application/Control Number: 14/214,480
Art Unit: 1674

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under pre-AIA 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of pre-AIA 35 U.S.C. 103(c) and potential pre-AIA 35 U.S.C. 102(e), (f) or (g) prior art under pre-AIA 35 U.S.C. 103(a).

Claim 16 and 21-27 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Sazani et al. (WO 2010/048586 A1, applicant's citation) in view of Hanson (US 2012/0289457 A1) and Harding et al. (*Molecular Therapy*, 2007, 15:157-166).

Sazani et al. disclose an antisense oligonucleotide SEQ ID NO:4 at page 79 as below:

Hu.DMD.Exon44.25.004 | GATCTGTCAAATCGCCTGCAGGTAA

The above sequence comprises the entire 22-mer sequence of SEQ ID NO:5 claimed in the instant case.

Sazani et al. teach that making a morpholino antisense oligonucleotide of "20-35" nucleotides in length such as 20, 21, and 22 nucleotides in length complementary to dystrophin exon 44. See claim 1 and page 41.

Sazani et al. teach that the intersubunit linkage has the structure shown in Figure 1A as below:

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as 25-mers that comprise the entire 20-mer sequence of the 20-mer antisense oligonucleotide.

See “M23D(+07-18)” and “M23D(+02-18)” in Table 1 as below:

M23D(+07-18)	GGC CAA ACC UCG GCU UAC CUG AAA U
M23D(+02-18)	GGC CAA ACC UCG GCU UAC CU

Harding et al. reported that the “20 and 25mers, M23D(+07-18) and M23D(+02-18), induced similar levels of murine dystrophin exon 23 skipping after *in vitro* transfection at concentrations of 200 nM or higher.” See page 160.

Regarding the oligomers of SEQ ID NOs:4, 5, and 6 and compositions comprising thereof, one of ordinary skill in the art would have been motivated, with a reasonable expectation of success, to shorten the length of Sazani’s 25-mer SEQ ID NO:4 to oligomers of 21, 22, and 23 nucleotides in length by truncating the 3’ end region of SEQ ID NO:4 so as to more economically synthesize dystrophin exon 44 skipping oligonucleotides at a reduced synthesis cost as compared to the cost of producing a 25-mer oligonucleotide, because it was known to synthesize dystrophin exon skipping oligonucleotides of 21, 22, and 23 nucleotides in length as taught by Sazani et al. (see claim 1 and page 41), and because 3’ end-truncated oligonucleotides of shorter lengths (e.g., 20-mer) were known to be as effective as longer oligonucleotides (e.g., 25-mer) in inducing dystrophin exon skipping such that both oligonucleotides “induced similar levels” of exon skipping as demonstrated by Harding et al.

In addition, since Sazani et al. provided only a finite number of identified, predictable exon skipping oligonucleotide length options, one of ordinary skill in the art would have reasonably pursued the finite number of known length options when making shorter versions of Sazani’s SEQ ID NO:4 as claimed in claim 4 (“antisense compound containing 20-35 morpholino subunits”) and as described at page 41 (“typically 15-25 bases”).

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“When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely that not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421, 82 USPQ2d 1385, 1397 (2007).

Accordingly, claims 16 and 21-27 taken as a whole would have been *prima facie* obvious at the time of the invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with

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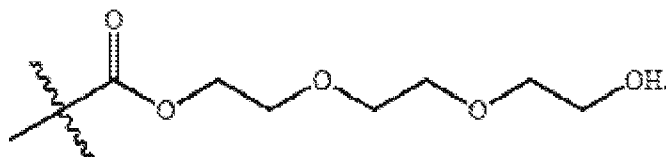
this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit <http://www.uspto.gov/forms/>. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to <http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp>.

Claims 16 and 21-27 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-32 of copending Application No. 8,779,128 B2 in view of Sazani et al. (WO 2010/048586 A1, applicant's citation) and Harding et al. (*Molecular Therapy*, 2007, 15:157-166).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are an obvious variation of and encompassed by the '128 patent claims drawn to a morpholino oligomer having the 5' terminus structure as claimed in claim 30 shown below:

30. The oligomer of claim 26, wherein R¹⁹ is piperiziny1 or



Note that the above structure is identical to the 5' terminus structure claimed in the instant claims.

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Now, the meaning of the “oligomer” claimed in the ‘128 patent claims reads on SEQ ID NO:22 disclosed in Table 11 of the ‘128 patent as below:

Exon44 -A	GATCTGTCAAATCGCCGCGAGGTAA	22
-----------	---------------------------	----

Note that the above sequence comprises the entire sequence of SEQ ID NOs:4, 5, and 6 claimed in the instant case. As such, the oligomer claimed in the '128 patent claims reads on SEQ ID NO:22 having the 5' terminus structure claimed in claim 30.

It would have been obvious to one of ordinary skill in the art to produce 3' end-truncated oligonucleotides of shorter lengths than SEQ ID NO:22 because it is more economical to synthesize shorter oligonucleotides, and because shorter oligonucleotides (e.g., 20-mer) were known to be as effective as longer oligonucleotides (e.g., 25-mer) in inducing dystrophin exon skipping such that both oligonucleotides “induced similar levels” of exon skipping as demonstrated by Harding et al., and because Sazani et al. expressly taught making dystrophin exon 44 skipping antisense oligonucleotides of at least 20 nucleotides in length. Accordingly, the instant claims would have been *prima facie* obvious over the '128 patent claims.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANA SHIN whose telephone number is (571)272-8008. The examiner can normally be reached on Monday through Thursday, 7am-5:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin
Primary Examiner
Art Unit 1674

/DANA SHIN/
Primary Examiner, Art Unit 1674



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United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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14/214,480

03/14/2014

Richard K. Bestwick

AVN-013B

3826

123147

7590

09/19/2014

Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

EXAMINER

SHIN, DANA H

ART UNIT

PAPER NUMBER

1674

NOTIFICATION DATE

DELIVERY MODE

09/19/2014

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipboston.docketing@nelsonmullins.com
chris.schlauch@nelsonmullins.com
ipqualityassuranceboston@nelsonmullins.com

Application No.
14/214,480
58414Applicant(s)
BESTWICK ET AL.**Office Action Summary**Examiner
DANA SHINArt Unit
1674AIA (First Inventor to File)
Status
No**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7-24-2014.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 1-21 is/are pending in the application.
 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☐ Claim(s) ____ is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
 Paper No(s)/Mail Date ____.
- 3) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. ____.
- 4) ☐ Other: ____.

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DETAILED ACTION

Election/Restrictions

All pending claims are drawn to an antisense oligomer. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species as set forth below.

Election of Species

This application contains claims directed to the following patentably distinct species:

1. Applicant is required to elect a single antisense oligomer sequence from SEQ ID NOs:1 and 4-8.
2. Applicant is required to elect a single arginine-rich peptide from SEQ ID NOs:24-39.

The species are independent or distinct because they are materially different. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 9, and 16 are generic.

There is a search and/or examination burden for the patentably distinct species as set forth above because at least the following reason(s) apply:

- 1) the species require a different field of search (for example, employing different search queries);
- 2) the prior art applicable to one species would not likely to be applicable to another species;
- 3) the species are likely to raise different non-prior art issues under 35 U.S.C. 112, first paragraph.

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Art Unit: 1674

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Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species or grouping of patentably indistinct species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species or grouping of patentably indistinct species.

Should applicant traverse on the ground that the species, or groupings of patentably indistinct species from which election is required, are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing them to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 or pre-AIA 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be corrected in compliance with 37 CFR 1.48(a) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. A request to correct inventorship under 37 CFR 1.48(a) must be accompanied by an application data sheet in accordance with 37 CFR 1.76 that identifies each inventor by his or her legal name and by the processing fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANA SHIN whose telephone number is (571)272-8008. The examiner can normally be reached on Monday through Thursday, 7am-5:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Babic can be reached on 571-272-8507. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DANA SHIN/
Primary Examiner, Art Unit 1674

SRPT-VYDS-0004225



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NOTICE OF ALLOWANCE AND FEE(S) DUE

123147 7590 07/07/2016
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

EXAMINER	
POLIAKOVA-GEORGA, EKATERINA	
ART UNIT	PAPER NUMBER
1674	

DATE MAILED: 07/07/2016

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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14/214,567 03/14/2014 Edward M. Kaye AVN-012BRCE 7395

TITLE OF INVENTION: COMPOSITIONS FOR TREATING MUSCULAR DYSTROPHY

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$480	\$0	\$0	\$480	10/07/2016

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL
#: 36419

Complete and send this form, together with applicable fee(s), to: **Mail** **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

123147 7590 07/07/2016
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/214,567	03/14/2014	Edward M. Kaye	AVN-012BRCE	7395

TITLE OF INVENTION: COMPOSITIONS FOR TREATING MUSCULAR DYSTROPHY

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$480	\$0	\$0	\$480	10/07/2016

EXAMINER	ART UNIT	CLASS-SUBCLASS
POLIAKOVA-GEORGA, EKATERINA	1674	514-04400A

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

1 _____

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☐ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ Applicant certifying micro entity status. See 37 CFR 1.29
☐ Applicant asserting small entity status. See 37 CFR 1.27
☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/214,567	03/14/2014	Edward M. Kaye	AVN-012BRCE	7395

EXAMINER
POLIAKOVA-GEORGA, EKATERINA

ART UNIT	PAPER NUMBER
1674	

DATE MAILED: 07/07/2016

123147 7590 07/07/2016
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 14/214,567	Applicant(s) KAYE, EDWARD M.	
	Examiner KATE POLIAKOVA	Art Unit 1674	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amended claims filed on 06/15/2016.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are 1,5-7,12,13,15,19,20,27-44,47 and 48. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a) ☐ All b) ☐ Some *c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date <u>03/03/2016, 06/15/2016</u> 3. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material 4. <input type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date _____ .	5. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 6. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 7. <input type="checkbox"/> Other _____.
---	---

/KATE POLIAKOVA/ Examiner, Art Unit 1674	/Tracy Vivlemore/ Primary Examiner, Art Unit 1674
---	--

Application/Control Number: 14/214,567
Art Unit: 1674

Page 2

The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

Terminal Disclaimer

The terminal disclaimer filed on 06/15/2016 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on pending reference Application Number 14/213,629 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Allowable Subject Matter

Claims 1, 5-7, 12, 13, 15, 19, 20, 27-44, 47 and 48 are allowed.

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance: previous rejections were based on publication of Clinical Trial NCT01540409, the publication date of which was assigned to 02/23/2012. As clarified by Applicant the publication is a cumulative document and only the latest version, published on October 14, 2014, which is after the effective filing date of instant Application, contains data such as length of treatment for more than 120 weeks, consideration of which would anticipate instant claims. Therefore the document is not available as prior art. There is no other prior art teaching treatment by eteplirsen for more than 120 weeks. Therefore previous 102 and 103 rejections are withdrawn. Further Applicant submitted proper Terminal Disclaimer, overcoming double patenting rejection.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATE POLIAKOVA whose telephone number is (571)270-5257. The examiner can normally be reached on Monday-Friday 8.30-5.00.

Application/Control Number: 14/214,567

Page 3

Art Unit: 1674

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia (Anna) Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KATE POLIAKOVA
Examiner
Art Unit 1674

/KATE POLIAKOVA/
Examiner, Art Unit 1674

/Tracy Vivlemore/
Primary Examiner, Art Unit 1674

SRPT-VYDS-0004232



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/214,567	03/14/2014	Edward M. Kaye	AVN-012B	7395

123147 7590 12/03/2015
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

EXAMINER

POLIAKOVA-GEORGAN, EKATERINA

ART UNIT	PAPER NUMBER
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1674

NOTIFICATION DATE	DELIVERY MODE
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12/03/2015

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipboston.docketing@nelsonmullins.com
chris.schlauch@nelsonmullins.com
ipqualityassuranceboston@nelsonmullins.com

Application No.
14/214,567
#: 86426Applicant(s)
KAYE, EDWARD M.**Office Action Summary**Examiner
KATE POLIAKOVAArt Unit
1674AIA (First Inventor to File)
Status
No**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/26/2015.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 1,5-7,12,13,15,19,20 and 27-48 is/are pending in the application.
 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1,5-7,12,13,15,19,20 and 27-48 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
 Paper No(s)/Mail Date 10/26/2015,11/04/2015.
- 3) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. ____.
- 4) ☐ Other: ____.

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Art Unit: 1674

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DETAILED ACTION

The present application is being examined under the pre-AIA first to invent provisions.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, 365(c), or 386(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of 35 U.S.C. 112(a) or the first paragraph of pre-AIA 35 U.S.C. 112, except for the best mode requirement. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994)

The disclosure of the prior-filed application, Application No. 61/793,463, fails to provide adequate support or enablement in the manner provided by 35 U.S.C. 112(a) or pre-AIA 35 U.S.C. 112, first paragraph for one or more claims of this application. Application No. 61/793,463 does not teach treatment with eteplirsen for more than 120 weeks. Therefore the priority date for instant claims 1, 5-7, 12, 13, 15, 19, 20, 27-48 is the actual filing date of instant application, 03/14/2014.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of pre-AIA 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5-7, 12, 13, 15, 19, 20, 27-41, 43-48 are rejected under pre-AIA 35 U.S.C. 102(b) as being anticipated by Clinical Trial NCT01540409 (ClinicalTrials.gov, published online on 02/23/2012, 4 pages) as evidenced by Clinical Trial NCT01396239, published online on 07/15/2011, 4 pages, of record).

Clinical Trial NCT01540409 discloses a method for treating Duchenne muscular dystrophy through induction of dystrophin expression by administration of eteplirsen in 50 mg/kg or 30 mg/kg dosing (see page 2) once weekly by infusion to patients of 7 to 13 years old for 212 weeks (see page 1). The patient to administer treatment are the ones who finished previous Clinical Trial NCT01396239, referred to as Study 4658-US-201 (see page 1), who have an out-of-frame deletion(s) that may be corrected by skipping exon 51 (see page 2 of NCT01396239), who receive treatment with oral corticosteroid for at least 24 weeks before eteplirsen treatment (see first paragraph on page 3 of NCT01396239).

Clinical Trial NCT01540409 further discloses that ambulation is measured by North Star Ambulatory Assessment (see page 2), disease progression is measured by 6 Minute Walk Test (see page 2), pulmonary function is measured by Maximum

Application/Control Number: 14/214,567
Art Unit: 1674

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Inspiratory Pressure or Maximum Expiratory Pressure or Forced Vital Capacity (see page 2) and level of dystrophin protein is measured by Western Blot analysis (see page 2).

Limitations of claims 31-33, 36, 38, 45-48 following “wherein” clause are expected to happen in the absence of evidence to the contrary.

Claim Rejections - 35 USC § 103

The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 41, 42 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Clinical Trial NCT01540409 (ClinicalTrials.gov, published online on 02/23/2012, 4 pages) as evidenced by Clinical Trial NCT01396239, published online on 07/15/2011, 4 pages, of record) and in further view of Manzur et al (Cochrane Database Syst Rev, 2004, 2: 1-71, cited from IDS).

Teachings from both Clinical Trials are discussed above.

Manzur et al teach that treatment of Duchenne muscular dystrophy with prednisolone or prednisone provides benefit to a patient (see Abstract and second column on page 4).

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It would have been obvious to one with ordinary skill in the art at the time of the invention to use both treatments for Duchenne muscular dystrophy as described by Clinical Trials and Manzur et al. One of the ordinary skill in the art would be motivated to do so because the treatments are provided for the same disease. It is obvious to combine things known separately to have same effect (see *In re Kerkhoven*, MPEP 2144.06).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit <http://www.uspto.gov/forms/>. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to <http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp>.

Claims 1, 6, 7, 13, 15, 18, 29-48 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-11, 14-19, 21-23 of copending Application No. 14/213,629. Although the claims at issue are not identical, they are not patentably distinct from each other because instant claims 1, 6, 7, 13, 15, 18, 29-48 claim essentially the same subject matter as claims 18, 21-23 from '629, because SEQ ID NO: 1 of '629 is the same as active ingredient of eteplirsén and the instant claims anticipate claims 1-11, 14-17, 19 of '629.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed 10/26/2015 have been fully considered but they are not persuasive.

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Art Unit: 1674

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Concerning 102 rejection Applicant argues that Clinical Trial NCT01396239 reference does not teach administration of eteplirsen for more than 120 weeks. In reply new reference, Clinical Trial NCT01540409, in the rejection above does teach the limitation.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATE POLIAKOVA whose telephone number is (571)270-5257. The examiner can normally be reached on Monday-Friday 8.30-5.00.

Application/Control Number: 14/214,567
Art Unit: 1674

Page 8

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KATE POLIAKOVA
Examiner
Art Unit 1674

/KATE POLIAKOVA/
Examiner, Art Unit 1674

/Tracy Vivlemore/
Primary Examiner, Art Unit 1674



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Alexandria, Virginia 22313-1450
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/214,567	03/14/2014	Edward M. Kaye	AVN-012B	7395

123147 7590 06/24/2015
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

EXAMINER

POLIAKOVA-GEORGA, EKATERINA

ART UNIT	PAPER NUMBER
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1674

NOTIFICATION DATE	DELIVERY MODE
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06/24/2015

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipboston.docketing@nelsonmullins.com
chris.schlauch@nelsonmullins.com
ipqualityassuranceboston@nelsonmullins.com

Application No.
14/214,567
#: 86435Applicant(s)
KAYE, EDWARD M.**Office Action Summary**Examiner
KATE POLIAKOVAArt Unit
1674AIA (First Inventor to File)
Status
No**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07/09/2014.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 1-26 is/are pending in the application.
 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-26 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
 Paper No(s)/Mail Date ____.
- 3) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. ____.
- 4) ☐ Other: ____.

Application/Control Number: 14/214,567

Page 2

Art Unit: 1674

The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) is acknowledged.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of pre-AIA 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-26 are rejected under pre-AIA 35 U.S.C. 102(b) as being anticipated by Clinical Trial NCT01396239 (ClinicalTrials.gov, published online on 07/15/2011, 4 pages).

Clinical Trial NCT01396239 discloses a method for treating Duchenne muscular dystrophy through induction of dystrophin expression by administration of eteplirsen in 50 mg/kg or 30 mg/kg dosing (see page 1) once weekly by single intravenous (i.v.) infusion to patients of 7 to 13 years old, having an out-of-frame deletion(s) that may be corrected by skipping exon 51 (see page 2), who receive treatment with oral corticosteroid for at least 24 weeks before eteplirsen treatment (see first paragraph on page 3).

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Page 3

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit <http://www.uspto.gov/forms/>. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to <http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp>.

Claims 1-4, 6-11, 13-18, 20-24 and 26 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-11, 14-19, 21-23 of copending Application No. 14/213,629. Although the claims at issue are not identical, they are not patentably distinct from each other because instant claims 1-4, 6-11, 13-18, 20-24 and 26 claim essentially the same subject matter as

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Art Unit: 1674

claims 18, 21-23 from '629, because SEQ ID NO: 1 of '629 is the same as active ingredient of eteplirsén and the instant claims anticipate claims 1-11, 14-17, 19 of '629.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATE POLIAKOVA whose telephone number is (571)270-5257. The examiner can normally be reached on Monday-Friday 8.30-5.00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KATE POLIAKOVA
Examiner
Art Unit 1674

/KATE POLIAKOVA/
Examiner, Art Unit 1674



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/223,634	03/24/2014	Stephen Donald Wilton	AVN-008CN22	8332

123147 7590 04/15/2015
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

EXAMINER

CHONG, KIMBERLY

ART UNIT	PAPER NUMBER
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1674

NOTIFICATION DATE	DELIVERY MODE
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04/15/2015

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipboston.docketing@nelsonmullins.com
chris.schlauch@nelsonmullins.com
ipqualityassuranceboston@nelsonmullins.com

Application No.
14/223,634
#: 86440Applicant(s)
WILTON ET AL.**Office Action Summary**Examiner
KIMBERLY CHONGArt Unit
1674AIA (First Inventor to File)
Status
No**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
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- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03/24/2014.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 1-14 is/are pending in the application.
 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☐ Claim(s) ____ is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

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Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
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 Paper No(s)/Mail Date ____.
- 3) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. ____.
- 4) ☐ Other: ____.

Application/Control Number: 14/223,634
Art Unit: 1674

Page 2

The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7 and 9-14, drawn to an antisense molecule capable of binding to a selected target site to induce exon skipping in the dystrophin gene set forth in SEQ ID No: 1 to 202, classifiable in class 536, subclass 24.5 (C12N 2310/11). This group is subject to a further restriction of antisense sequences and exon target.
- II. Claim 8, drawn to a method of treating muscular dystrophy in a patient comprising administering a composition comprising an antisense molecule capable of binding to an exon target site, classifiable in class 514, subclass 44 (A61K 48/00). This group is subject to a further restriction of antisense sequences and exon target.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product

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antisense can be used in a materially different process, such as in an *in situ* hybridization assay. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

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Page 4

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Furthermore, should applicants elect to prosecute groups I and II, these groups are subject to further restriction as follows. Claims 1-6 are subject to an additional restriction since it is not considered to be a proper genus/Markush. See MPEP 803.02 – PRACTICE RE MARKUSH-TYPE CLAIMS – if the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claims on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 300 (CCPA 1980); and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. In *re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structure feature disclosed as being essential to that utility.

Claims 1-6 specifically claims antisense molecules or a combination of two antisense molecules targeted to specific exons of the dystrophin gene. Each sequence

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is considered to be unrelated, since each sequence claimed is structurally and functionally independent and distinct. Furthermore, a search of more than two (2) sequences claimed in claims 1-6 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than two (2) of the claimed sequences. In view of the foregoing, two (2) sequences are considered to be a reasonable number of sequences for examination. Accordingly, applicants are required to elect a total of two (2) sequences from claims 1-6. Note that this is not a species election.

Claims 1-6 specifically claims different exons of the dystrophin gene that are targeted by antisense molecules. Each exon is considered to be unrelated, since each exon claimed is structurally and functionally independent and distinct and can be targeted and modulated by different antisense sequences. Furthermore, a search of more than one (1) exon target claimed in claims 1-6 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed exon targets. In view of the foregoing, one (1) exon target is considered to be a reasonable number of exon targets for examination. Accordingly, applicants are required to elect a total of one (1) exon target from claims 1-6. Note that this is not a species election.

Please note: election of the antisense sequences must be commensurate in scope with the election of the exon target (the antisense sequence must target the elected exon target).

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The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Kimberly Chong** whose telephone number is **571-272-3111**. The examiner can normally be reached Monday thru Friday between 9-5 pm.

If attempts to reach the examiner by telephone are unsuccessful please contact the SPE for 1674 Mark Shibuya at 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent

Application/Control Number: 14/223,634
Art Unit: 1674

Page 8

Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Kimberly Chong/
Primary Examiner
Art Unit 1674



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/273,318	05/08/2014	Stephen Donald WILTON	AVN-008CN23	5117
123147	7590	10/20/2014		
Nelson Mullins Riley & Scarborough LLP/Sarepta One Post Office Square Boston, MA 02109			EXAMINER CHONG, KIMBERLY	
			ART UNIT	PAPER NUMBER
			1674	
			NOTIFICATION DATE	DELIVERY MODE
			10/20/2014	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipboston.docketing@nelsonmullins.com
chris.schlauch@nelsonmullins.com
ipqualityassuranceboston@nelsonmullins.com

Application No.
14/273,318
#: 86449Applicant(s)
WILTON ET AL.**Office Action Summary**Examiner
KIMBERLY CHONGArt Unit
1674AIA (First Inventor to File)
Status
No**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
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Status

- 1) ☒ Responsive to communication(s) filed on 07/23/2014.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 2-7 is/are pending in the application.
 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 2-7 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

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Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

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- 4) ☐ Other: ____.

Application/Control Number: 14/273,318
Art Unit: 1674

Page 2

The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed 07/23/2014 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 07/03/2014 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

With entry of the amendment filed on 07/23/2014, claims 2-7 are pending in the application.

Information Disclosure Statement

The submission of the Information Disclosure Statement on 07/23/2014 is in compliance with 37 CFR 1.97. The information disclosure statement has been considered by the examiner and signed copies have been placed in the file.

Response to Declaration

The declaration filed on 07/23/2014 under 37 CFR 1.132 providing evidence of the claimed oligonucleotides unexpected superior ability will not be addressed with respect to the previous rejections as these rejections were withdrawn.

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With respect to the new grounds of rejection the declaration is insufficient to overcome the new 103 rejection. Applicant submits the data show that instantly claimed 30-mer oligonucleotide having SEQ ID No. 181 induced skipping of exon 51 in excess of 100-times more than the 18-mer oligonucleotide h51AON1 of van Deutekom. This ability of a 30-mer morpholino antisense oligonucleotide to induce exon skipping is not unexpected based on the 103 rejection herein, particularly with respect to the teachings of Summerton et al.

New Claim Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-7 are rejected under pre-AIA 35 U.S.C. 103(a) as being obvious over van Deutekom (U.S. Patent No. 7,534,879 of record), Summerton et al. (Biochemica et Biophysica Acta 1489 , 1999, 141-158), Baker et al. (US Application 20050048495), Hudziak et al. (US 20030166588) and Iversen et al. (Clinical Cancer Research, July 2003, Vol. 9, 2510-2519).

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under pre-AIA 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The claims are drawn to an antisense oligonucleotide of 30 bases comprising the base sequence SEQ ID No. 181 wherein the uracil bases are thymine bases and wherein the antisense oligonucleotide is a morpholino antisense oligonucleotide chemically linked to a polyethylene glycol chain and drawn to a pharmaceutical composition comprising said antisense oligonucleotide.

Claim interpretation:

With respect to the claimed antisense oligonucleotide comprising thymine bases, Table 1A in the instant specification teach substitution of a U by a T would be using other antisense chemistries such as peptide nucleic acids or morpholinos “(TABLE-US-00001 [0051] TABLE 1A Description of 2'-O-methyl phosphorothioate antisense oligonucleotides that have been used to date to study induced exon skipping during the processing of the dystrophin pre-mRNA. Since these 2'-O-methyl antisense oligonucleotides are more RNA-like, U represents uracil. With other antisense chemistries such as peptide nucleic acids or morpholinos, these U bases may be shown as "T")”.

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Thus the limitation wherein the uracil bases are substituted with thymine bases is being interpreted only in the context of the antisense oligonucleotide having chemistries such as morpholinos as described in the instant specification. The claimed antisense oligonucleotide is a morpholino antisense oligonucleotide wherein the uracil bases are thymine bases to represent the morpholino moiety.

van Deutekom et al. claim the following:

1. An isolated oligonucleotide of between 20 to 50 nucleotides comprising a sequence consisting of SEQ ID: 27.

3. The isolated oligonucleotide of claim 1, wherein the oligonucleotide is a peptide nucleic acid, locked nucleic acid, and/or morpholino phosphorodiamidate oligonucleotide.

van Deutekom et al. teach SEQ ID No. 27 is a 20 mer oligonucleotide having the sequence ucaaggaagauggcauuucu which is identical to 20 nucleotides of the claimed SEQ ID No. 181 and further teach pharmaceutical compositions comprising said oligonucleotide. van Deutekom et al. do not specifically exemplify an oligonucleotide having 30 bases that comprise the 20 nucleotide sequence of SEQ ID No. 27, wherein the oligonucleotide is a morpholino and linked to a polyethylene glycol chain.

Summerton et al. teach one advantage to using morpholino antisense oligonucleotides is that there is no difficulty in predicting effective targets as compared to antisense oligonucleotides without morpholino subunits (see page 145). Summerton et al. further teach that when using long morpholino oligonucleotides, one can achieve both high efficacy and high specificity, which is often not thought to be possible using

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antisense oligonucleotides with phosphorothioate chemistries (see page 149 4.3.2). As shown in Figure 4, morpholino antisense oligonucleotides 25 and 30 nucleotides in length had significantly greater inhibition as compared to oligonucleotides having 20 nucleotides in length. Summerton et al. further demonstrates that longer oligonucleotides with morpholino subunits were more efficient at correcting splicing of a pre-mRNA (see Figure 6). Figure 6 shows that a 28-mer morpholino oligonucleotide significantly corrected splicing of a thalassemic pre-mRNA as compared to an 18-mer oligonucleotide comprising modifications of PNA, morpholino subunits or 2'-O-methyl RNA. Thus Summerton provides motivation to increase the length of the 20-mer oligonucleotide taught by van Deutekom et al. to generate a more efficient and target specific oligonucleotide.

Baker et al. teach antisense oligonucleotide molecules comprising conjugates such as polyethylene glycol chemically linked to the antisense oligonucleotide enhance the activity, cellular distribution and cellular uptake of the oligonucleotides (see 0094).

Hudziak et al. teach the use of morpholino antisense oligonucleotides to correct natural mRNA splice processing in methods of treating or preventing a disease state wherein the oligonucleotide contains a polyethylene glycol chain to enhance the solubility of the compound (see 0154). Hudziak et al. describes morpholino oligomers as oligonucleotides composed of morpholino subunits that lack a ribose backbone linked to a phosphodiester bond (see 0031).

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It is well known in the prior art that morpholino antisense oligonucleotides are described as DNA analogs wherein the sequence of the morpholino antisense has thymine bases substituted for uracil bases (see Iverson et al, Table 1 on page 2511).

It would have been obvious for one of ordinary skill in the art to make a 30-mer morpholino oligonucleotide targeted to exon 51 wherein the oligonucleotide comprised the 20 nucleotides taught by van Deutekom et al. van Deutekom et al. teach inducing exon skipping in the DMD gene can restore dystrophin synthesis in up to 80% of treated cells, thereby providing methods of treatment for DMD (see columns 5 and 6). van Deutekom et al. demonstrably teach targeting an exon internal region of exon 51 using an oligonucleotide having SEQ ID No. 27 induced exon skipping. This region targeted by the antisense oligonucleotide of van Deutekom et al. is within the annealing site of the exon 51 target gene which SEQ ID No. 181 binds (see H51A(+66+95) on page 16 of the instant specification).

Given this finding by van Deutekom et al. and the teaching of Summerton et al., one of skill in the art would have used the oligonucleotide taught by van Deutekom et al., represented as SEQ ID No. 27, to make a 30-mer oligonucleotide comprising morpholino subunits to induce exon skipping of exon 51 more efficiently because a 30-mer morpholino oligonucleotide was shown by Summerton et al. to be more efficient than shorter oligonucleotides targeted to the same region.

It would have further been obvious to one of ordinary skill in the art to represent the morpholino antisense oligonucleotide using thymine bases instead of uracil bases because it was well known in the art that morpholino oligomers are DNA analog

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oligomers that do not have a ribose backbone, as taught by Hudziak et al. and therefore when annotating the sequence of the morpholino oligonucleotide, uracil bases would be substituted with thymine bases, as shown by Iversen et al.

One of ordinary skill in the art would have chemically linked a polyethylene glycol chain to the morpholino oligonucleotide to enhance the delivery and solubility of the oligonucleotide for use in methods of treatment as demonstrated by Hudziak et al. and Baker et al.

One of ordinary skill in the art would have expected to be capable of making a 30-mer antisense oligonucleotide with a reasonable expectation that this oligonucleotide would achieve both high efficacy and high specificity to the target region of exon 51 to induce exon skipping as shown by Summerton et al.

Thus in the absence of evidence to the contrary, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Applicants argument regarding van Deutekom et al. is warranted as this reference was used in the new grounds of rejection above.

Applicant argues there is nothing in van Deutekom et al. about substituting uracil bases in RNA oligonucleotides with thymine bases and further the term DNA appears nowhere in the context of an antisense oligonucleotide having natural DNA bases. In response, as stated above, the limitation wherein the uracil bases are substituted with thymine bases is being interpreted only in the context of the antisense oligonucleotide

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having chemistries such as morpholinos as described in the instant specification. There is nothing in the instant specification that limits the uracil bases as being substituted with natural DNA thymine bases; the only thymine base substitution mentioned is in the context of morpholino and PNA molecules.

Applicant argues the Examiner improperly used the instant specification as prior art to infer teachings into van Deutekom et al. that are not in fact disclosed in van Deutekom et al. In response, MPEP 2111.01 states: “The ordinary and customary meaning of a term may be evidenced by a variety of sources, including the words of the claims themselves, the specification, drawings, and prior art. However, the best source for determining the meaning of a claim term is the specification - the greatest clarity is obtained when the specification serves as a glossary for the claim terms. The presumption that a term is given its ordinary and customary meaning may be rebutted by the applicant by clearly setting forth a different definition of the term in the specification.” [emphasis added]

In the instant application, the phrase “uracil bases are thymine bases” is defined in the specification as referring to morpholino antisense oligonucleotides as instantly claimed. Applicant has not rebutted this by clearly setting forth a different definition of the phrase in the specification. Thus the use of the instant specification to define the phrase above was proper. van Deutekom clearly teach an antisense oligonucleotide wherein the oligonucleotide is a morpholino oligonucleotide, which is known to be represented in the prior art using thymine bases instead of uracil bases. Moreover, even if Applicant rebuts the definition in the instant specification, the rejection above

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clearly provides motivation for substituting thymine bases when referring to a morpholino antisense oligonucleotide, given the morpholine moieties are known in the prior art as DNA analogs.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2-7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8-9 of U.S. Application 14/316,603. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of the patent are drawn to patently indistinguishable subject matter.

Response to Arguments

Claim Rejections - 35 USC § 102

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The rejection of Claims 2 and 5 under 35 U.S.C. 102(e) as being anticipated by van Deutekom et al. (U.S. Patent No. 7,534,879) is withdrawn.

Response to Applicant's argument is moot with respect to this rejection.

Claim Rejections - 35 USC § 103

The rejection of claims 2-7 under pre-AIA 35 U.S.C. 103(a) as being obvious over van Deutekom (U.S. Patent No. 7,534,879), Baker et al. (US Application 20050048495), and Matteucci, M. (Perspectives in Drug Disc. and Design, 1996, vol. 4, pp 1-16) is withdrawn.

Response to Applicant's argument is moot as this combination of references was not used in the new grounds of rejection above.

Double Patenting

The rejection of claims 2-7 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 7,807,816 is maintained.

The rejection of claims 2-7 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 7,960,541 is maintained.

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Applicant argues the Examiner has failed to establish a motivation in the prior art for one of ordinary skill in the art to modify the claimed antisense oligonucleotides of the '816 and '541 patents to make the presently claimed antisense oligonucleotide. This argument is not persuasive, the instantly claimed antisense oligonucleotide having 30 nucleotides comprising a morpholino moiety is explicitly claimed as one of the genus of oligonucleotides and a motivation to modify the antisense oligonucleotide is not required. Thus the instant application and Patents '816 and '541 describe patentably indistinguishable subject matter.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Kimberly Chong** whose telephone number is **571-272-3111**. The examiner can normally be reached Monday thru Friday between 9-5 pm.

If attempts to reach the examiner by telephone are unsuccessful please contact the SPE for 1674 Christopher Babic at 571-272-8507. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image

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problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Kimberly Chong/
Primary Examiner
Art Unit 1674



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/273,318	05/08/2014	Stephen Donald WILTON	AVN-008CN23	5117
123147	7590	07/03/2014		
Nelson Mullins Riley & Scarborough LLP/Sarepta One Post Office Square Boston, MA 02109			EXAMINER CHONG, KIMBERLY	
			ART UNIT	PAPER NUMBER
			1674	
			NOTIFICATION DATE	DELIVERY MODE
			07/03/2014	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipboston.docketing@nelsonmullins.com
chris.schlauch@nelsonmullins.com
ipqualityassuranceboston@nelsonmullins.com

Application No.
14/273,318
#: 58463Applicant(s)
WILTON ET AL.**Office Action Summary**Examiner
KIMBERLY CHONGArt Unit
1674AIA (First Inventor to File)
Status
No**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06/18/2014.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 2-7 is/are pending in the application.
 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 2-7 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☒ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 11/570,691.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
 Paper No(s)/Mail Date 06/18/2014.
- 3) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. ____.
- 4) ☐ Other: ____.

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The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

Status of the Application

Claims 2-7 are pending and currently under examination.

Information Disclosure Statement

The submission of the Information Disclosure Statement on 06/18/2014 is in compliance with 37 CFR 1.97. The information disclosure statement has been considered by the examiner and signed copies have been placed in the file.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of pre-AIA 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 2 and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by van Deutekom et al. (U.S. Patent No. 7,534,879).

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The claims are drawn to an antisense oligonucleotide of 30 bases comprising the base sequence SEQ ID No. 181 wherein the uracil bases are thymine bases and wherein the antisense oligonucleotide is a morpholino antisense oligonucleotide. The claims are further drawn to a pharmaceutical composition comprising said antisense oligonucleotide.

van Deutekom et al. claim the following:

1. An isolated oligonucleotide of between 20 to 50 nucleotides comprising a sequence consisting of SEQ ID: 27.

3. The isolated oligonucleotide of claim 1, wherein the oligonucleotide is a peptide nucleic acid, locked nucleic acid, and/or morpholino phosphorodiamidate oligonucleotide.

SEQ ID No. 27 is a 20 mer oligonucleotide having the sequence ucaaggaagauggcauuucu which is identical to 20 nucleotides of the claimed SEQ ID No. 181 and teach pharmaceutical compositions comprising said oligonucleotide.

With respect to instant claims 2 and 5 reciting the oligonucleotide has 30 bases comprising the base sequence of SEQ ID No. 181, van Deutekom teach a genus of oligonucleotides targeted to exon 51 wherein the oligonucleotides are complementary to a consecutive part of between 16 and 50 nucleotides of an exon 51 (see column 6) and teach the exon internal region of exon 51 targeted by an 20-mer oligonucleotide was a region of exon 51 that was capable of binding said oligonucleotide which induced exon 51 skipping. This region targeted by the antisense oligonucleotide of van Deutekom et al. is within the annealing site of the exon 51 target gene which SEQ ID No. 181 binds (see H51A(+66+95) on page 16 of the instant specification). MPEP 2131.02 states that

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if one of ordinary skill in the art is able to “at once envisage” the specific compound within a genus, the compound is anticipated.

2131.02 Genus-Species Situations [R-11.2013]

III. A GENERIC DISCLOSURE WILL ANTICIPATE A CLAIMED SPECIES COVERED BY THAT DISCLOSURE WHEN THE SPECIES CAN BE “AT ONCE ENVISAGED” FROM THE DISCLOSURE

“[W]hether a generic disclosure necessarily anticipates everything within the genus ... depends on the factual aspects of the specific disclosure and the particular products at issue.” *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1083, 89 USPQ2d 1370, 1375 (Fed. Cir. 2008). See also *Osram Sylvania Inc. v. American Induction Tech.*, 701 F.3d 698, 706, 105 USPQ2d 1368, 1374 (Fed. Cir. 2012) (“how one of ordinary skill in the art would understand the relative size of a genus or species in a particular technology is of critical importance”).

For example, when a claimed compound is not specifically named in a reference, but instead it is necessary to select portions of leachings within the reference and combine them, e.g., select various substituents from a list of alternatives given for placement at specific sites on a generic chemical formula to arrive at a specific composition, anticipation can only be found if the classes of substituents are sufficiently limited or well delineated. *Ex parte A*, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990). If one of ordinary skill in the art is able to “at once envisage” the specific compound within the generic chemical formula, the compound is anticipated. One of ordinary skill in the art must be able to draw the structural formula or write the name of each of the compounds included in the generic formula before any of the compounds can be “at once envisaged.” One may look to the preferred embodiments to determine which compounds can be anticipated. *In re Petering*, 301 F.2d 676, 133 USPQ 275 (CCPA 1962).

Given that van Deutekom et al. teach oligonucleotides of 16 to 50 nucleotides in length that are complementary to an exon internal region of exon 51 and demonstrates this region was capable of binding an antisense oligonucleotide of 20 nucleotides in length (SEQ ID No. 27) that induced exon 51 skipping and further given the sequence of exon 51 is known in the prior art, one of ordinary skill in the art would clearly be able to

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envisage an oligonucleotide of 30 nucleotides that is complementary to exon 51 within the same target region.

With respect to the claimed antisense oligonucleotide comprising thymine bases, Table 1A in the instant specification teach substitution of a U by a T would be using other antisense chemistries such as peptide nucleic acids or morpholinos “(TABLE-US-00001 [0051] TABLE 1A Description of 2'-O-methyl phosphorothioate antisense oligonucleotides that have been used to date to study induced exon skipping during the processing of the dystrophin pre-mRNA. Since these 2'-O-methyl antisense oligonucleotides are more RNA-like, U represents uracil. With other antisense chemistries such as peptide nucleic acids or morpholinos, these U bases may be shown as "T")”. Given van Deutekom et al. teach that the oligonucleotide can comprise different types of nucleic acids (which would be DNA or RNA) and teach modifications such as peptide nucleic acids or morpholinos, van Deutekom et al. essentially teach an oligonucleotide wherein uracil bases are thymine bases based on the instant specification.

Thus van Deutekom anticipates the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 2-7 are rejected under pre-AIA 35 U.S.C. 103(a) as being obvious over van Deutekom (U.S. Patent No. 7,534,879), Baker et al. (US Application 20050048495), and Matteucci, M. (Perspectives in Drug Disc. and Design, 1996, vol. 4, pp 1-16).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under pre-AIA 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The claims are drawn to an antisense oligonucleotide of 30 bases comprising the base sequence SEQ ID No. 181 wherein the uracil bases are thymine bases and wherein the antisense oligonucleotide is a morpholino antisense oligonucleotide. The claims are further drawn to the oligonucleotide being chemically linked to one or more moieties or conjugates and drawn to a pharmaceutical composition comprising said antisense oligonucleotide.

van Deutekom et al. claim the following:

1. An isolated oligonucleotide of between 20 to 50 nucleotides comprising a sequence consisting of SEQ ID: 27.

3. The isolated oligonucleotide of claim 1, wherein the oligonucleotide is a peptide nucleic acid, locked nucleic acid, and/or morpholino phosphorodiamidate oligonucleotide.

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SEQ ID No. 27 is a 20 mer oligonucleotide having the sequence ucaaggaagauggcauuucu which is identical to 20 nucleotides of the claimed SEQ ID No. 181 and teach pharmaceutical compositions comprising said oligonucleotide. With respect to instant claims 2 and 5 reciting the oligonucleotide has 30 bases comprising the base sequence of SEQ ID No. 181, van Deutekom et al. teach a genus of oligonucleotides targeted to exon 51 wherein the oligonucleotides are complementary to a consecutive part of between 16 and 50 nucleotides of an exon 51 (see column 6) and teach the exon internal region of exon 51 targeted by an 20-mer oligonucleotide was a region of exon 51 that was capable of binding said oligonucleotide which induced exon 51 skipping. This region targeted by the antisense oligonucleotide of van Deutekom et al. is within the annealing site of the exon 51 target gene which SEQ ID No. 181 binds (see H51A(+66+95) on page 16 of the instant specification). MPEP 2131.02 states that if one of ordinary skill in the art is able to “at once envisage” the specific compound within a genus, the compound is anticipated.

2131.02 Genus-Species Situations [R-11.2013]

III. A GENERIC DISCLOSURE WILL ANTICIPATE A CLAIMED SPECIES COVERED BY THAT DISCLOSURE WHEN THE SPECIES CAN BE “AT ONCE ENVISAGED” FROM THE DISCLOSURE

“[W]hether a generic disclosure necessarily anticipates everything within the genus ... depends on the factual aspects of the specific disclosure and the particular products at issue.” *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1083, 89 USPQ2d 1370, 1375 (Fed. Cir. 2008). See also *Osram Sylvania Inc. v. American Induction Tech.*, 701 F.3d 698, 706, 105 USPQ2d 1368, 1374 (Fed. Cir. 2012) (“how one of ordinary skill in the art would understand the relative size of a genus or species in a particular technology is of critical importance”).

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For example, when a claimed compound is not specifically named in a reference, but instead it is necessary to select portions of teachings within the reference and combine them, e.g., select various substituents from a list of alternatives given for placement at specific sites on a generic chemical formula to arrive at a specific composition, anticipation can only be found if the classes of substituents are sufficiently limited or well delineated. *Ex parte A*, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990). If one of ordinary skill in the art is able to “at once envisage” the specific compound within the generic chemical formula, the compound is anticipated. One of ordinary skill in the art must be able to draw the structural formula or write the name of each of the compounds included in the generic formula before any of the compounds can be “at once envisaged.” One may look to the preferred embodiments to determine which compounds can be anticipated. *In re Petering*, 301 F.2d 676, 133 USPQ 275 (CCPA 1962).

Given that van Deutekom et al. teach oligonucleotides of 16 to 50 nucleotides in length that are complementary to an exon internal region of exon 51 and demonstrates this region was capable of binding an antisense oligonucleotide of 20 nucleotides in length (SEQ ID No. 27) that induced exon 51 skipping and further given the sequence of exon 51 is known in the prior art, one of ordinary skill in the art would clearly be able to envisage an oligonucleotide of 30 nucleotides that is complementary to exon 51 within the same target region.

van Deutekom et al et al. do not specifically teach an oligonucleotide comprising conjugates as claimed.

Baker et al. teach antisense oligonucleotide molecules comprising conjugates such as polyethylene glycol chemically linked to the antisense oligonucleotide enhance the activity, cellular distribution and cellular uptake of the oligonucleotides (see 0094).

It would have been obvious for one of ordinary skill in the art to incorporate the modifications taught by Baker et al. into the oligonucleotide taught by van Deutekom et al. Based on the advantages taught by Baker et al. such as increased binding affinity

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and enhanced activity, cellular distribution and cellular uptake of the oligonucleotides, one of ordinary skill in the art would have clearly been motivated and would have expected to be capable of making a molecule with these modifications.

With respect to the claimed antisense oligonucleotide comprising thymine bases, Table 1A in the instant specification teach substitution of a U by a T would be using other antisense chemistries such as peptide nucleic acids or morpholinos “(TABLE-US-00001 [0051] TABLE 1A Description of 2'-O-methyl phosphorothioate antisense oligonucleotides that have been used to date to study induced exon skipping during the processing of the dystrophin pre-mRNA. Since these 2'-O-methyl antisense oligonucleotides are more RNA-like, U represents uracil. With other antisense chemistries such as peptide nucleic acids or morpholinos, these U bases may be shown as "T")”. Given van Deutekom et al. teach that the oligonucleotide can comprise different types of nucleic acids (which would be DNA or RNA) and teach modifications such as peptide nucleic acids or morpholinos, van Deutekom et al. essentially teach an oligonucleotide wherein uracil bases are thymine bases.

Moreover, it is well known in the art that antisense oligonucleotides comprising thymine bases enhance the affinity of the oligonucleotides to the target sequence as compared to uracil bases (see Matteucci at page 10). It would have been further obvious for one of ordinary skill in the art to substitute thymine bases for the uracil bases in the antisense oligonucleotide taught by van Deutekom et al. One of skill in the art would have wanted to maximize the binding affinity of the antisense oligonucleotide to the target exon for more efficient exon skipping and would have therefore

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incorporated thymine bases in place of uracil bases for increased affinity as taught by Matteucci. One of ordinary skill in the art would have expected to be capable of making this base substitution, the steps of which are routine to the skilled artisan.

Thus in the absence of evidence to the contrary, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2-7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 7,807,816. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of the patent are drawn to patently indistinguishable subject matter.

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Claims 2-7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 7,960,541. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of the patent are drawn to patently indistinguishable subject matter.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Kimberly Chong** whose telephone number is **571-272-3111**. The examiner can normally be reached Monday thru Friday between 9-5 pm.

If attempts to reach the examiner by telephone are unsuccessful please contact the SPE for 1674 Christopher Babic at 571-272-8507. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has

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been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Kimberly Chong/
Primary Examiner
Art Unit 1674



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/273,379	05/08/2014	Stephen Donald WILTON	AVN-008CN24	1002
123147	7590	07/07/2014		
Nelson Mullins Riley & Scarborough LLP/Sarepta One Post Office Square Boston, MA 02109			EXAMINER CHONG, KIMBERLY	
			ART UNIT	PAPER NUMBER
			1674	
			NOTIFICATION DATE	DELIVERY MODE
			07/07/2014	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipboston.docketing@nelsonmullins.com
chris.schlauch@nelsonmullins.com
ipqualityassuranceboston@nelsonmullins.com

Application No.
14/273,379
#: 86478Applicant(s)
WILTON ET AL.**Office Action Summary**Examiner
KIMBERLY CHONGArt Unit
1674AIA (First Inventor to File)
Status
No**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06/24/2014.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 2-7 is/are pending in the application.
 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 2-7 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 05/08/2014, 06/25/2014 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☒ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 11570691.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
 Paper No(s)/Mail Date 06/24/2014.
- 3) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. ____.
- 4) ☐ Other: ____.

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The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

Status of the Application

Claims 2-7 are pending and currently under examination.

Information Disclosure Statement

The submission of the Information Disclosure Statement on 04/07/2009 is in compliance with 37 CFR 1.97. The information disclosure statement has been considered by the examiner and signed copies have been placed in the file.

Claim Rejections - 35 USC § 112

The following is a quotation of 35 U.S.C. 112(b):

(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-7 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

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Claims 2 and 5 recite "wherein the target region is annealing site H53A(+23+47), annealing site H53A(+39+69), or both, wherein the antisense oligonucleotide base sequence comprises at least 20 consecutive bases of ...(SEQ ID NO: 193)". This limitation is indefinite because it requires the antisense to anneal to two different annealing sites and comprise 20 bases of SEQ ID No. 193. The nucleotide sequence having SEQ ID No. 193 would not anneal to the annealing site H53A(+23+47), as demonstrated by the specification in table on page 16 of the instant specification. This table lists an entirely different oligonucleotide sequence that anneals to H53A(+23+47) and does not have at least 20 identical sequences to SEQ ID No. 193. Thus it is unclear how 20 nucleotides of the claimed antisense oligonucleotide can anneal to both annealing sites that have different sequences.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of pre-AIA 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 2 and 5 are rejected under pre-AIA 35 U.S.C. 102(e) as being anticipated by van Ommen (US Application 20060147952 cited on IDS filed 03/20/2014) and evidence by Matsuo et al. (US 6,653,467).

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The claims are drawn to an isolated antisense oligonucleotide of 25 bases comprising a base sequence to a target region consisting of 25 consecutive nucleotides of exon 53 of the human dystrophin pre-mRNA, wherein the target region H53A(+23+47), annealing site H53A(+39+69), or both, wherein the antisense oligonucleotide base sequence comprises at least 20 consecutive bases of ...(SEQ ID NO: 193), wherein uracil bases are thymine bases, wherein the antisense oligonucleotide is a morpholino antisense oligonucleotide and wherein the antisense induces exon 53 skipping. The claims are further drawn to a pharmaceutical composition comprising said antisense oligonucleotide.

van Ommen teach an oligonucleotide having SEQ ID No. 29 that is 18 nucleotides in length identical to the claimed SEQ ID No. 193. van Ommen teach the oligonucleotide can comprise modified nucleotides such as 2'-O-methyl, a morpholine ring, peptide nucleic acids and locked nucleic acids (see paragraph 0019).

van Ommen teach in [0018] oligonucleotides that are complementary to a consecutive part of between 16 and 50 nucleotides of an exon RNA and teach different types of nucleic acid molecules can be used to generate the oligonucleotide.

[0020] The complementary oligonucleotide generated through a method of the invention is preferably complementary to a consecutive part of between 16 and 50 nucleotides of the exon RNA. Different types of nucleic acid may be used to generate the oligonucleotide.

van Ommen teach in [0015 and 0016] the use of oligonucleotides to skip exons such as exon 53. In paragraph [0019] it is taught that the oligonucleotide can have modifications such as morpholino phosphorodiamidate, peptide nucleic acid and locked

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nucleic acids, for example, and further teach the oligonucleotide comprises modified internucleoside linkages.

[0019] With the advent of nucleic acid-mimicking technology, it has become possible to generate molecules that have a similar, preferably the same, hybridization characteristics, in kind, not necessarily in amount, as nucleic acid itself. Such equivalents are, of course, also part of the invention. Examples of such mimics equivalents are peptide nucleic acid, locked nucleic acid and/or a morpholino phosphorodiamidate...Hybrids between one or more of the equivalents among each other and/or together with nucleic acid are, of course, also part of the invention. In a preferred embodiment, an equivalent comprises locked nucleic acid, as locked nucleic acid displays a higher target affinity and reduced toxicity and, therefore, shows a higher efficiency of exon skipping.

van Ommen teach in [0018] that the oligonucleotide preferably comprises RNA, which would mean that the oligonucleotide is also DNA. Thus while van Ommen teach a preferred embodiment of RNA oligonucleotides, DNA oligonucleotides are also taught and finds support on page 10 of the specification which discusses examples of DNA oligonucleotides known in the prior art e.g. oligonucleotides containing locked nucleic acids (DNA analogs). As evidenced by Matsuo et al., the term “oligonucleotide” is known in the art to as DNA or RNA (see column 9).

MPEP 2123 states in part:

A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. Merck & Co. v. Biocraft Laboratories, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also > Upsher-Smith Labs. v. PamLab, LLC, 412 F.3d 1319, 1323, 75 USPQ2d 1213, 1215 (Fed. Cir. 2005)(reference disclosing optional inclusion of a particular component teaches compositions that both do and do not contain that component); < Celeritas Technologies Ltd. v. Rockwell International Corp., 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998) (The court held that the prior art anticipated the claims even though it taught away from the claimed invention. “The fact that a modem with a single carrier data signal is shown to be less than optimal does not vitiate the fact that it is disclosed.”).{emphasis added}

Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423

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(CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994) (The invention was directed to an epoxy impregnated fiber-reinforced printed circuit material. The applied prior art reference taught a printed circuit material similar to that of the claims but impregnated with polyester-imide resin instead of epoxy. The reference, however, disclosed that epoxy was known for this use, but that epoxy impregnated circuit boards have "relatively acceptable dimensional stability" and "some degree of flexibility," but are inferior to circuit boards impregnated with polyester-imide resins. The court upheld the rejection concluding that applicant's argument that the reference teaches away from using epoxy was insufficient to overcome the rejection since "Gurley asserted no discovery beyond what was known in the art." 27 F.3d at 554, 31 USPQ2d at 1132.). Furthermore, "[t]he prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed...." *In re Fulton*, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004). [emphasis added].

van Ommen reasonably teach to one having ordinary skill in the art nonpreferred embodiments of DNA oligonucleotides that are complementary to a target sequence of exon 53.

With respect to instant claims 2 and 5 reciting an oligonucleotide comprising at least 25 bases of SEQ ID No. 193 targeted to annealing site H53A(+39+69), van Ommen teach a genus of oligonucleotides targeted to exon 53 wherein the oligonucleotides are complementary to a consecutive part of between 16 and 50 nucleotides of an exon 53 (see 0018) and teach the exon internal region of exon 53 targeted by an 18-mer oligonucleotide was a region of exon 53 that was capable of binding an oligonucleotide which induced exon 53 skipping. This region targeted by the antisense oligonucleotide of van Ommen et al. is within the claimed H53A(+39+69) annealing site. MPEP 2131.02 states that if one of ordinary skill in the art is able to "at once envisage" the specific compound within a genus, the compound is anticipated.

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III. A GENERIC DISCLOSURE WILL ANTICIPATE A CLAIMED SPECIES COVERED BY THAT DISCLOSURE WHEN THE SPECIES CAN BE “AT ONCE ENVISAGED” FROM THE DISCLOSURE

“[W]hether a generic disclosure necessarily anticipates everything within the genus ... depends on the factual aspects of the specific disclosure and the particular products at issue.” *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1083, 89 USPQ2d 1370, 1375 (Fed. Cir. 2008). See also *Osram Sylvania Inc. v. American Induction Tech.*, 701 F.3d 698, 706, 105 USPQ2d 1368, 1374 (Fed. Cir. 2012) (“how one of ordinary skill in the art would understand the relative size of a genus or species in a particular technology is of critical importance”).

For example, when a claimed compound is not specifically named in a reference, but instead it is necessary to select portions of leachings within the reference and combine them, e.g., select various substituents from a list of alternatives given for placement at specific sites on a generic chemical formula to arrive at a specific composition, anticipation can only be found if the classes of substituents are sufficiently limited or well delineated. *Ex parte A*, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990). If one of ordinary skill in the art is able to “at once envisage” the specific compound within the generic chemical formula, the compound is anticipated. One of ordinary skill in the art must be able to draw the structural formula or write the name of each of the compounds included in the generic formula before any of the compounds can be “at once envisaged.” One may look to the preferred embodiments to determine which compounds can be anticipated. *In re Petering*, 301 F.2d 676, 133 USPQ 275 (CCPA 1962).

Given that van Ommen et al. teach oligonucleotides of 16 to 50 nucleotides in length that are complementary to an exon internal region of exon 53 and demonstrates this region was capable of binding antisense oligonucleotides that induced exon 53 skipping and further given the sequence of exon 53 is known in the prior art, one of ordinary skill in the art would clearly be able to envisage an oligonucleotide of at least 25 nucleotides that is complementary to H53A(+39+69) annealing site of exon 53.

With respect to the claimed antisense oligonucleotide optionally comprising thymine bases, Table 1A in the instant specification teach substitution of a U by a T

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would be using other antisense chemistries such as peptide nucleic acids or morpholinos "(TABLE-US-00001 [0051] TABLE 1A Description of 2'-O-methyl phosphorothioate antisense oligonucleotides that have been used to date to study induced exon skipping during the processing of the dystrophin pre-mRNA. Since these 2'-O-methyl antisense oligonucleotides are more RNA-like, U represents uracil. With other antisense chemistries such as peptide nucleic acids or morpholinos, these U bases may be shown as "T")". Given van Ommen et al. teach that the oligonucleotide can comprise different types of nucleic acids (which would be DNA or RNA) and teach modifications such as peptide nucleic acids or morpholinos, van Ommen et al. essentially teach an oligonucleotide wherein uracil bases are optionally thymine bases.

Thus van Ommen anticipates the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-7 are rejected under pre-AIA 35 U.S.C. 103(a) as being obvious over van Ommen (US Application 20060147952), Baker et al. (US Application 20050048495), Matteucci, M. (Perspectives in Drug Disc. and Design, 1996, vol. 4, pp 1-16) and Matsuo et al. (US 6,653,467).

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under pre-AIA 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The claims are drawn to an isolated antisense oligonucleotide of 25 bases comprising a base sequence to a target region consisting of 25 consecutive nucleotides of exon 53 of the human dystrophin pre-mRNA, wherein the target region H53A(+23+47), annealing site H53A(+39+69), or both, wherein the antisense oligonucleotide base sequence comprises at least 20 consecutive bases of ...(SEQ ID NO: 193), wherein uracil bases are thymine bases, wherein the antisense oligonucleotide is a morpholino antisense oligonucleotide and wherein the antisense induces exon 53 skipping. The claims are further drawn to the oligonucleotide being chemically linked to one or more moieties or conjugates and drawn to a pharmaceutical composition comprising said antisense oligonucleotide.

van Ommen teach an oligonucleotide having SEQ ID No. 29 that has 18 nucleotides identical to the claimed SEQ ID No. 193. van Ommen teach the oligonucleotide can comprise modified nucleotides such as 2'-O-methyl, a morpholine ring, peptide nucleic acids and locked nucleic acids (see paragraph 0019).

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van Ommen teach in [0018] oligonucleotides that are complementary to a consecutive part of between 16 and 50 nucleotides of an exon RNA and teach different types of nucleic acid molecules can be used to generate the oligonucleotide.

[0018] The complementary oligonucleotide generated through a method of the invention is preferably complementary to a consecutive part of between 16 and 50 nucleotides of the exon RNA. Different types of nucleic acid may be used to generate the oligonucleotide.

van Ommen teach in [0015] and [0016] the use of oligonucleotides to skip exons such as exon 53. In paragraph [0019] it is taught that the oligonucleotide can have modifications such as morpholino phosphorodiamidate, peptide nucleic acid and locked nucleic acids, for example, and further teach the oligonucleotide comprises modified internucleoside linkages.

[0019] With the advent of nucleic acid-mimicking technology, it has become possible to generate molecules that have a similar, preferably the same, hybridization characteristics, in kind, not necessarily in amount, as nucleic acid itself. Such equivalents are, of course, also part of the invention. Examples of such mimics equivalents are peptide nucleic acid, locked nucleic acid and/or a morpholino phosphorodiamidate...Hybrids between one or more of the equivalents among each other and/or together with nucleic acid are, of course, also part of the invention. In a preferred embodiment, an equivalent comprises locked nucleic acid, as locked nucleic acid displays a higher target affinity and reduced toxicity and, therefore, shows a higher efficiency of exon skipping.

van Ommen et al. do not specifically teach an oligonucleotide comprising conjugates as claimed.

Baker et al. teach antisense oligonucleotide molecules comprising conjugates such as polyethylene glycol chemically linked to the antisense oligonucleotide enhance the activity, cellular distribution and cellular uptake of the oligonucleotides (see 0094).

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It would have been obvious for one of ordinary skill in the art to incorporate the modifications taught by Baker et al. into the oligonucleotide taught by van Ommen. Based on the advantages taught by Baker et al. such as increased binding affinity and enhanced activity, cellular distribution and cellular uptake of the oligonucleotides, one of ordinary skill in the art would have clearly been motivated and would have expected to be capable of making a molecule with these modifications.

With respect to the claimed oligonucleotide comprising at least 20 bases of SEQ ID No. 193, van Ommen teach a genus of oligonucleotides targeted to exon 53 wherein the oligonucleotides are complementary to a consecutive part of between 16 and 50 nucleotides of an exon 53 (see 0018) and teach the exon internal region of exon 53 targeted by an 18-mer oligonucleotide was a region of exon 53 that was capable of binding an oligonucleotide which induced exon 53 skipping. This region targeted by the antisense oligonucleotide of van Ommen et al. is within the claimed H53A(+39+69) annealing site. MPEP 2131.02 states that if one of ordinary skill in the art is able to “at once envisage” the specific compound within a genus, the compound is anticipated.

2131.02 Genus-Species Situations [R-11.2013]

III. A GENERIC DISCLOSURE WILL ANTICIPATE A CLAIMED SPECIES COVERED BY THAT DISCLOSURE WHEN THE SPECIES CAN BE “AT ONCE ENVISAGED” FROM THE DISCLOSURE

“[W]hether a generic disclosure necessarily anticipates everything within the genus ... depends on the factual aspects of the specific disclosure and the particular products at issue.” *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1083, 89 USPQ2d 1370, 1375 (Fed. Cir. 2008). See also *Osram Sylvania Inc. v. American Induction Tech.*, 701 F.3d 698, 706, 105 USPQ2d 1368, 1374 (Fed. Cir. 2012) (“how one of ordinary skill in the art would understand the relative size of a genus or species in a particular technology is of critical importance”).

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Art Unit: 1674

For example, when a claimed compound is not specifically named in a reference, but instead it is necessary to select portions of teachings within the reference and combine them, e.g., select various substituents from a list of alternatives given for placement at specific sites on a generic chemical formula to arrive at a specific composition, anticipation can only be found if the classes of substituents are sufficiently limited or well delineated. *Ex parte A*, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990). If one of ordinary skill in the art is able to “at once envisage” the specific compound within the generic chemical formula, the compound is anticipated. One of ordinary skill in the art must be able to draw the structural formula or write the name of each of the compounds included in the generic formula before any of the compounds can be “at once envisaged.” One may look to the preferred embodiments to determine which compounds can be anticipated. *In re Petering*, 301 F.2d 676, 133 USPQ 275 (CCPA 1962).

Given that van Ommen et al. teach oligonucleotides of 16 to 50 nucleotides in length that are complementary to exon 53 and the sequence of exon 53 is known in the prior art and further teach an oligonucleotide having 18 identical nucleotides of the claimed SEQ ID No. 193, one of ordinary skill in the art is clearly able to envisage an oligonucleotide of at least 25 nucleotides complementary to exon 53. One would have been motivated to make any oligonucleotide of 16 to 50 nucleotides targeted to the known specific target region of exon 53 wherein van Ommen et al. demonstrates exon skipping. As evidenced by Matsuo et al., it was known in the prior art that antisense oligonucleotides longer than 18 nucleotides in length were capable of inducing exon skipping (see columns 10 and 11).

With respect to the claimed antisense oligonucleotide optionally comprising thymine bases, Table 1A in the instant specification teach substitution of a U by a T would be using other antisense chemistries such as peptide nucleic acids or morpholinos “(TABLE-US-00001 [0051] TABLE 1A Description of 2'-O-methyl phosphorothioate antisense oligonucleotides that have been used to date to study

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induced exon skipping during the processing of the dystrophin pre-mRNA. Since these 2'-O-methyl antisense oligonucleotides are more RNA-like, U represents uracil. With other antisense chemistries such as peptide nucleic acids or morpholinos, these U bases may be shown as "T"). Given van Ommen et al. teach that the oligonucleotide can comprise different types of nucleic acids (which would be DNA or RNA) and teach modifications such as peptide nucleic acids or morpholinos, it would be obvious for van Ommen et al. to incorporate such a modification and thus van Ommen et al. essentially teach an oligonucleotide wherein uracil bases are optionally thymine bases.

Moreover, it is well known in the art that antisense oligonucleotides comprising thymine bases enhance the affinity of the oligonucleotides to the target sequence as compared to uracil bases (see Matteucci at page 10). It would have been further obvious for one of ordinary skill in the art to substitute thymine bases for the uracil bases in the antisense oligonucleotide taught by van Ommen et al. One of skill in the art would have wanted to maximize the binding affinity of the antisense oligonucleotide to the target exon for more efficient exon skipping and would have therefore incorporated thymine bases in place of uracil bases for increased affinity as taught by Matteucci. One of ordinary skill in the art would have expected to be capable of making this base substitution, the steps of which are routine to the skilled artisan.

Thus in the absence of evidence to the contrary, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2-7 are provisionally rejected under the judicially created doctrine of double patenting over claims 21-49 of copending Application No. 14/086,859. This is a provisional double patenting rejection since the conflicting claims have not yet been patented. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of the patent are drawn to patently indistinguishable subject matter.

Claims 2-7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36 of U.S. Patent No. 8,455,636. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of the patent are drawn to patently indistinguishable subject matter.

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Claims 2-7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 8,232,384. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of the patent are drawn to patently indistinguishable subject matter.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Kimberly Chong** whose telephone number is **571-272-3111**. The examiner can normally be reached Monday thru Friday between 9-5 pm.

If attempts to reach the examiner by telephone are unsuccessful please contact the SPE for 1674 Christopher Babic at 571-272-8507. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has

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been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Kimberly Chong/
Primary Examiner
Art Unit 1674



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

123147 7590 03/10/2015
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

EXAMINER	
CHONG, KIMBERLY	
ART UNIT	PAPER NUMBER
1674	

DATE MAILED: 03/10/2015

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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14/316,603 06/26/2014 Stephen Donald Wilton AVN-008CN25 2157

TITLE OF INVENTION: ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$480	\$0	\$0	\$480	06/10/2015

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL
#: 36493

Complete and send this form, together with applicable fee(s), to: **Mail** **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

123147 7590 03/10/2015
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

14/316,603

06/26/2014

Stephen Donald Wilton

AVN-008CN25

2157

TITLE OF INVENTION: ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
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nonprovisional

SMALL

\$480

\$0

\$0

\$480

06/10/2015

EXAMINER	ART UNIT	CLASS-SUBCLASS
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CHONG, KIMBERLY

1674

514-044000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

1 _____

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

☐ Issue Fee☐ Publication Fee (No small entity discount permitted)☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

☐ A check is enclosed.☐ Payment by credit card. Form PTO-2038 is attached.

☐ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29☐ Applicant asserting small entity status. See 37 CFR 1.27☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/316,603	06/26/2014	Stephen Donald Wilton	AVN-008CN25	2157

EXAMINER
CHONG, KIMBERLY

ART UNIT	PAPER NUMBER
1674	

DATE MAILED: 03/10/2015

123147 7590 03/10/2015
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

<i>Examiner-Initiated Interview Summary</i>	Application No. 14/316,603	Applicant(s) WILTON ET AL.	
	Examiner KIMBERLY CHONG	Art Unit 1674	

All participants (applicant, applicant's representative, PTO personnel):

(1) KIMBERLY CHONG. (3) ____.

(2) AMY MANDRAGOURAS. (4) ____.

Date of Interview: 23 February 2015.

Type: ☒ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☐ No.
If Yes, brief description: ____.

Issues Discussed ☐ 101 ☐ 112 ☐ 102 ☐ 103 ☒ Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: ____.

Identification of prior art discussed: ____.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

The Examiner stated the claims were in condition for allowance except for the double patenting rejection. Applicant will file a terminal disclaimer over Patents 7,807,816, 7,960,541, and 8,489,907 and will expressly abandon co-pending application 12/273,318 because this application has identical claims to the pending claims.

Applicant recordation instructions: It is not necessary for applicant to provide a separate record of the substance of interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

/KIMBERLY CHONG/ Primary Examiner, Art Unit 1674	
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Notice of Allowability	Application No. 14/316,603	Applicant(s) WILTON ET AL.	
	Examiner KIMBERLY CHONG	Art Unit 1674	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 02/26/2015.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are 8,9. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
Certified copies:
a) ☒ All b) ☐ Some *c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 11/570,691.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date <u>See Continuation Sheet</u> 3. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material 4. <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date <u>02/23/2015</u> .	5. <input type="checkbox"/> Examiner's Amendment/Comment 6. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 7. <input type="checkbox"/> Other _____.
--	--

/KIMBERLY CHONG/
Primary Examiner, Art Unit 1674

Continuation Sheet (PTOL-37)

Application No. 14/316,603

Continuation of Attachment(s) 2. Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date: 12/23/2014,02/26/2015.

Application/Control Number: 14/316,603
Art Unit: 1674

Page 2

The present application is being examined under the pre-AIA first to invent provisions.

The following is an examiner's statement of reasons for allowance:

Applicant submits arguments against the 103 rejection of record and argues one of ordinary skill in the art would not have selected h51AON1 as a lead compound and would not have been motivated to lengthen this compound.

The Examiner maintains that one of skill would have selected h51AON1 as a lead compound for exon 51 skipping as van Deutekom teach only two compounds that target exon 51 and teach several experiments demonstrating the efficiency of exon skipping using h51AON1 however Applicant's arguments against the motivation to lengthen h51AON1 are sufficient to overcome the rejection of record.

The Terminal Disclaimer filed 02/26/2015 has been approved and the Double Patenting rejection over 7,807,816, 7,960,541 and 8,486,907 has been withdrawn. Co-pending application 12/273,318 has been expressly abandoned by Applicant and therefore the Double Patenting rejection is moot.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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Page 3

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Kimberly Chong** whose telephone number is **571-272-3111**. The examiner can normally be reached Monday thru Friday between 9-5 pm.

If attempts to reach the examiner by telephone are unsuccessful please contact the SPE for 1674 Mark Shibuya at 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Kimberly Chong/
Primary Examiner
Art Unit 1674

Application/Control Number: 14/316,603
Art Unit: 1674

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/316,603	06/26/2014	Stephen Donald Wilton	AVN-008CN25	2157
123147	7590	09/26/2014		
Nelson Mullins Riley & Scarborough LLP/Sarepta One Post Office Square Boston, MA 02109			EXAMINER CHONG, KIMBERLY	
			ART UNIT 1674	PAPER NUMBER
			NOTIFICATION DATE 09/26/2014	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipboston.docketing@nelsonmullins.com
chris.schlauch@nelsonmullins.com
ipqualityassuranceboston@nelsonmullins.com

Application No.
14/316,603
#: 88503Applicant(s)
WILTON ET AL.**Office Action Summary**Examiner
KIMBERLY CHONGArt Unit
1674AIA (First Inventor to File)
Status
No**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08/11/2014.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 8 and 9 is/are pending in the application.
 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 8 and 9 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 06/26/2014 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☒ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 11/570,691.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
 Paper No(s)/Mail Date 08/26/14, 07/18/14, 06/30/14.
- 3) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. ____.
- 4) ☐ Other: ____.

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The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

Status of the Application

Claims 8 and 9 are pending and currently under examination.

Information Disclosure Statement

The Information Disclosure Statements submitted on 06/30/2014 and 08/26/2014 are in compliance with 37 CFR 19.7. The information disclosure statements have been considered by the examiner and signed copies have been placed in the file.

The Information Disclosure Statement filed 07/18/2014 is not in compliance. With respect to the Foreign Patent Documents, only the documents with English abstracts are considered as indicated. The documents lined thru (#45, 46 and 49) have not been considered because the name of the Patentee has not been provided.

Claim Rejections - 35 USC § 103

The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 8 and 9 are rejected under pre-AIA 35 U.S.C. 103(a) as being obvious over van Deutekom (U.S. Patent No. 7,534,879 of record), Summerton et al. (Biochemica et Biophysica Acta 1489 , 1999, 141-158), Baker et al. (US Application 20050048495), Hudziak et al. (US 20030166588) and Iversen et al. (Clinical Cancer Research, July 2003, Vol. 9, 2510-2519).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under pre-AIA 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The claims are drawn to an antisense oligonucleotide of 30 bases comprising the base sequence SEQ ID No. 181 wherein the uracil bases are thymine bases and wherein the antisense oligonucleotide is a morpholino antisense oligonucleotide chemically linked to a polyethylene glycol chain and drawn to a pharmaceutical composition comprising said antisense oligonucleotide.

Claim interpretation:

With respect to the claimed antisense oligonucleotide comprising thymine bases, Table 1A in the instant specification teach substitution of a U by a T would be using other antisense chemistries such as peptide nucleic acids or morpholinos “(TABLE-US-

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00001 [0051] TABLE 1A Description of 2'-O-methyl phosphorothioate antisense oligonucleotides that have been used to date to study induced exon skipping during the processing of the dystrophin pre-mRNA. Since these 2'-O-methyl antisense oligonucleotides are more RNA-like, U represents uracil. With other antisense chemistries such as peptide nucleic acids or morpholinos, these U bases may be shown as "T").

Thus the limitation wherein the uracil bases are substituted with thymine bases is being interpreted only in the context of the antisense oligonucleotide having chemistries such as morpholinos as described in the instant specification. The claimed antisense oligonucleotide is a morpholino antisense oligonucleotide wherein the uracil bases are thymine bases to represent the morpholino moiety.

van Deutekom et al. claim the following:

1. An isolated oligonucleotide of between 20 to 50 nucleotides comprising a sequence consisting of SEQ ID: 27.

3. The isolated oligonucleotide of claim 1, wherein the oligonucleotide is a peptide nucleic acid, locked nucleic acid, and/or morpholino phosphorodiamidate oligonucleotide.

van Deutekom et al. teach SEQ ID No. 27 is a 20 mer oligonucleotide having the sequence ucaaggaagauggcauuucu which is identical to 20 nucleotides of the claimed SEQ ID No. 181 and further teach pharmaceutical compositions comprising said oligonucleotide. van Deutekom et al. do not specifically exemplify an oligonucleotide having 30 bases that comprise the 20 nucleotide sequence of SEQ ID No. 27, wherein the oligonucleotide is a morpholino and linked to a polyethylene glycol chain.

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Summerton et al. teach one advantage to using morpholino antisense oligonucleotides is that there is no difficulty in predicting effective targets as compared to antisense oligonucleotides without morpholino subunits (see page 145). Summerton et al. further teach that when using long morpholino oligonucleotides, one can achieve both high efficacy and high specificity, which is often not thought to be possible using antisense oligonucleotides with phosphorothioate chemistries (see page 149 4.3.2). As shown in Figure 4, morpholino antisense oligonucleotides 25 and 30 nucleotides in length had significantly greater inhibition as compared to oligonucleotides having 20 nucleotides in length. Summerton et al. further demonstrates that longer oligonucleotides with morpholino subunits were more efficient at correcting splicing of a pre-mRNA (see Figure 6). Figure 6 shows that a 28-mer morpholino oligonucleotide significantly corrected splicing of a thalassemic pre-mRNA as compared to an 18-mer oligonucleotide comprising modifications of PNA, morpholino subunits or 2'-O-methyl RNA. Thus Summerton provides motivation to increase the length of the 20-mer oligonucleotide taught by van Deutekom et al. to generate a more efficient and target specific oligonucleotide.

Baker et al. teach antisense oligonucleotide molecules comprising conjugates such as polyethylene glycol chemically linked to the antisense oligonucleotide enhance the activity, cellular distribution and cellular uptake of the oligonucleotides (see 0094).

Hudziak et al. teach the use of morpholino antisense oligonucleotides to correct natural mRNA splice processing in methods of treating or preventing a disease state wherein the oligonucleotide contains a polyethylene glycol chain to enhance the

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solubility of the compound (see 0154). Hudziak et al. describes morpholino oligomers as oligonucleotides composed of morpholino subunits that lack a ribose backbone linked to a phosphodiester bond (see 0031).

It is well known in the prior art that morpholino antisense oligonucleotides are described as DNA analogs wherein the sequence of the morpholino antisense has thymine bases substituted for uracil bases (see Iverson et al, Table 1 on page 2511).

It would have been obvious for one of ordinary skill in the art to make a 30-mer morpholino oligonucleotide targeted to exon 51 wherein the oligonucleotide comprised the 20 nucleotides taught by van Deutekom et al. van Deutekom et al. teach inducing exon skipping in the DMD gene can restore dystrophin synthesis in up to 80% of treated cells, thereby providing methods of treatment for DMD (see columns 5 and 6). van Deutekom et al. demonstrably teach targeting an exon internal region of exon 51 using an oligonucleotide having SEQ ID No. 27 induced exon skipping. This region targeted by the antisense oligonucleotide of van Deutekom et al. is within the annealing site of the exon 51 target gene which SEQ ID No. 181 binds (see H51A(+66+95) on page 16 of the instant specification).

Given this finding by van Deutekom et al. and the teaching of Summerton et al., one of skill in the art would have used the oligonucleotide taught by van Deutekom et al., represented as SEQ ID No. 27, to make a 30-mer oligonucleotide comprising morpholino subunits to induce exon skipping of exon 51 more efficiently because a 30-mer morpholino oligonucleotide was shown by Summerton et al. to be more efficient than shorter oligonucleotides targeted to the same region.

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It would have further been obvious to one of ordinary skill in the art to represent the morpholino antisense oligonucleotide using thymine bases instead of uracil bases because it was well known in the art that morpholino oligomers are DNA analog oligomers that do not have a ribose backbone, as taught by Hudziak et al. and therefore when annotating the sequence of the morpholino oligonucleotide, uracil bases would be substituted with thymine bases, as shown by Iversen et al.

One of ordinary skill in the art would have chemically linked a polyethylene glycol chain to the morpholino oligonucleotide to enhance the delivery and solubility of the oligonucleotide for use in methods of treatment as demonstrated by Hudziak et al. and Baker et al.

One of ordinary skill in the art would have expected to be capable of making a 30-mer antisense oligonucleotide with a reasonable expectation that this oligonucleotide would achieve both high efficacy and high specificity to the target region of exon 51 to induce exon skipping as shown by Summerton et al.

Thus in the absence of evidence to the contrary, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

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1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 8 and 9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 7,807,816. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of the patent are drawn to patently indistinguishable subject matter.

Claims 8 and 9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 7,960,541. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of the patent are drawn to patently indistinguishable subject matter.

Claims 8 and 9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-31 of U.S. Patent No. 8,486,907. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of the patent are drawn to patently indistinguishable subject matter. It would have been obvious to use

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the instantly claimed oligonucleotide in the methods of Patent '907 to induce exon skipping of exon 51.

Claims 8 and 9 are provisionally rejected under the judicially created doctrine of double patenting over claims 2-7 of copending Application No. 14/273,318. This is a provisional double patenting rejection since the conflicting claims have not yet been patented. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of the patent are drawn to patently indistinguishable subject matter. This is a provisional obviousness-type double patenting rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Kimberly Chong** whose telephone number is **571-272-3111**. The examiner can normally be reached Monday thru Friday between 9-5 pm.

If attempts to reach the examiner by telephone are unsuccessful please contact the SPE for 1674 Christopher Babic at 571-272-8507. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Kimberly Chong/
Primary Examiner
Art Unit 1674



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NOTICE OF ALLOWANCE AND FEE(S) DUE

123147 7590 03/16/2015
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

EXAMINER

CHONG, KIMBERLY

ART UNIT

PAPER NUMBER

1674

DATE MAILED: 03/16/2015

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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14/316,609

06/26/2014

Stephen Donald Wilton

AVN-008CN26

4848

TITLE OF INVENTION: ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$480	\$0	\$0	\$480	06/16/2015

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL
#: 36514

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Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
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CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

123147 7590 03/16/2015
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I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/316,609	06/26/2014	Stephen Donald Wilton	AVN-008CN26	4848

TITLE OF INVENTION: ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$480	\$0	\$0	\$480	06/16/2015

EXAMINER	ART UNIT	CLASS-SUBCLASS
CHONG, KIMBERLY	1674	536-024500

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

1 _____

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☐ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ Applicant certifying micro entity status. See 37 CFR 1.29
☐ Applicant asserting small entity status. See 37 CFR 1.27
☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/316,609	06/26/2014	Stephen Donald Wilton	AVN-008CN26	4848

EXAMINER
CHONG, KIMBERLY

ART UNIT	PAPER NUMBER
1674	

DATE MAILED: 03/16/2015

123147 7590 03/16/2015
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

36517

<i>Applicant-Initiated Interview Summary</i>	Application No.	Applicant(s)	
	14/316,609	WILTON ET AL.	
	Examiner	Art Unit	
	KIMBERLY CHONG	1674	

All participants (applicant, applicant's representative, PTO personnel):

(1) KIMBERLY CHONG. (3) ____.

(2) AMY MANDRAGOURAS. (4) ____.

Date of Interview: 03 March 2015.

Type: ☒ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☐ No.
If Yes, brief description: ____.

Issues Discussed ☐101 ☐112 ☐102 ☐103 ☐Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: ____.

Identification of prior art discussed: ____.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Discussed rejections of record. Claims are in condition for allowance except for the double patenting rejection which Applicant agreed to file a Terminal Disclaimer.

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

/KIMBERLY CHONG/ Primary Examiner, Art Unit 1674	
---	--

Summary of Record of Interview Requirements**Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record**

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Notice of Allowability	Application No. 14/316,609	Applicant(s) WILTON ET AL.	
	Examiner KIMBERLY CHONG	Art Unit 1674	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 03/03/2015.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are 8 and 9. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a) ☐ All b) ☐ Some *c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

<ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date <u>See Continuation Sheet</u> 3. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material 4. <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date <u>03/03/2015</u>. 	<ol style="list-style-type: none"> 5. <input type="checkbox"/> Examiner's Amendment/Comment 6. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 7. <input type="checkbox"/> Other _____.
--	--

Continuation Sheet (PTOL-37)

Application No. 14/316,609

Continuation of Attachment(s) 2. Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date: 03/03/2015,01/21/2015.

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Art Unit: 1674

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The present application is being examined under the pre-AIA first to invent provisions.

The following is an examiner's statement of reasons for allowance:

Applicant submits arguments against the 103 rejection of record and argues one of ordinary skill in the art would not have selected h53AON1 as a lead compound and would not have been motivated to lengthen this compound.

Applicant's arguments against the motivation to lengthen h53AON1 are sufficient to overcome the rejection of record.

The Terminal Disclaimer filed 03/03/2015 has been approved and the Double Patenting rejection over 8,455,636 and 8,232,384 has been withdrawn.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Kimberly Chong** whose telephone number is **571-272-3111**. The examiner can normally be reached Monday thru Friday between 9-5 pm.

Application/Control Number: 14/316,609
Art Unit: 1674

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If attempts to reach the examiner by telephone are unsuccessful please contact the SPE for 1674 Mark Shibuya at 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Kimberly Chong/
Primary Examiner
Art Unit 1674



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/316,609	06/26/2014	Stephen Donald Wilton	AVN-008CN26	4848
123147	7590	10/21/2014		
Nelson Mullins Riley & Scarborough LLP/Sarepta One Post Office Square Boston, MA 02109			EXAMINER CHONG, KIMBERLY	
			ART UNIT	PAPER NUMBER
			1674	
			NOTIFICATION DATE	DELIVERY MODE
			10/21/2014	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipboston.docketing@nelsonmullins.com
chris.schlauch@nelsonmullins.com
ipqualityassuranceboston@nelsonmullins.com

Application No.
14/316,609
#: 88524Applicant(s)
WILTON ET AL.**Office Action Summary**Examiner
KIMBERLY CHONGArt Unit
1674AIA (First Inventor to File)
Status
No**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08/11/2014.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 8 and 9 is/are pending in the application.
 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 8 and 9 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 06/26/2014 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
 Paper No(s)/Mail Date 6/30/14, 7/18/14, 8/26/14.
- 3) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. ____.
- 4) ☐ Other: ____.

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The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

Status of the Application

Claims 8 and 9 are pending and currently under examination.

Information Disclosure Statement

The submission of the Information Disclosure Statements on 06/30/2014, 07/18/2014 and 08/26/2014 is in compliance with 37 CFR 19.7. The information disclosure statements have been considered by the examiner and signed copies have been placed in the file.

Claim Rejections - 35 USC § 103

The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8 and 9 are rejected under pre-AIA 35 U.S.C. 103(a) as being obvious over van Ommen (US Application 20060147952 of record), Summerton et al. (Biochemica et Biophysica Acta 1489 , 1999, 141-158), Baker et al. (US Application

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20050048495), Hudziak et al. (US 20030166588) and Iversen et al. (Clinical Cancer Research, July 2003, Vol. 9, 2510-2519).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under pre-AIA 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The claims are drawn to an isolated antisense oligonucleotide of 25 bases comprising a base sequence to a target region consisting of 25 consecutive nucleotides of exon 53 of the human dystrophin pre-mRNA, wherein the target region is H53A(+23+47) and annealing site H53A(+39+69) wherein the antisense oligonucleotide base sequence comprises at least 20 consecutive bases of ...(SEQ ID NO: 193), wherein uracil bases are thymine bases, wherein the antisense oligonucleotide is a morpholino antisense oligonucleotide, wherein the antisense oligonucleotide is chemically linked to a polyethylene glycol chain and wherein the antisense induces exon 53 skipping. The claims are further drawn to a pharmaceutical composition comprising said antisense oligonucleotide.

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Claim interpretation:

With respect to the claimed antisense oligonucleotide comprising thymine bases, Table 1A in the instant specification teach substitution of a U by a T would be using other antisense chemistries such as peptide nucleic acids or morpholinos “(TABLE-US-00001 [0051] TABLE 1A Description of 2'-O-methyl phosphorothioate antisense oligonucleotides that have been used to date to study induced exon skipping during the processing of the dystrophin pre-mRNA. Since these 2'-O-methyl antisense oligonucleotides are more RNA-like, U represents uracil. With other antisense chemistries such as peptide nucleic acids or morpholinos, these U bases may be shown as "T")”.

Thus the limitation wherein the uracil bases are substituted with thymine bases is being interpreted only in the context of the antisense oligonucleotide having chemistries such as morpholinos as described in the instant specification. The claimed antisense oligonucleotide is a morpholino antisense oligonucleotide wherein the uracil bases are thymine bases to represent the morpholino moiety.

van Ommen teach an oligonucleotide having SEQ ID No. 29 that has 18 nucleotides identical to the claimed SEQ ID No. 193. van Ommen teach the oligonucleotide can comprise modified nucleotides such as 2'-O-methyl, a morpholine ring, peptide nucleic acids and locked nucleic acids (see paragraph 0019). van Ommen teach in [0018] oligonucleotides that are complementary to a consecutive part of between 16 and 50 nucleotides of an exon RNA and teach different types of nucleic acid molecules can be used to generate the oligonucleotide.

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van Ommen teach in [0015] and [0016] the use of oligonucleotides to skip exons such as exon 53. In paragraph [0019] it is taught that the oligonucleotide can have modifications such as morpholino phosphorodiamidate, peptide nucleic acid and locked nucleic acids, for example, and further teach the oligonucleotide comprises modified internucleoside linkages.

van Ommen et al. do not specifically exemplify an oligonucleotide having 25 bases that comprise the 20 nucleotide sequence of SEQ ID No. 29, wherein the oligonucleotide is a morpholino and linked to a polyethylene glycol chain.

Summerton et al. teach one advantage to using morpholino antisense oligonucleotides is that there is no difficulty in predicting effective targets as compared to antisense oligonucleotides without morpholino subunits (see page 145). Summerton et al. further teach that when using long morpholino oligonucleotides, one can achieve both high efficacy and high specificity, which is often not thought to be possible using antisense oligonucleotides with phosphorothioate chemistries (see page 149 4.3.2). As shown in Figure 4, morpholino antisense oligonucleotides 25 nucleotides in length had significantly greater inhibition as compared to oligonucleotides having 20 nucleotides in length. Summerton et al. further demonstrates that longer oligonucleotides with morpholino subunits were more efficient at correcting splicing of a pre-mRNA (see Figure 6). Figure 6 shows that a 28-mer morpholino oligonucleotide significantly corrected splicing of a thalassemic pre-mRNA as compared to an 18-mer oligonucleotide comprising modifications of PNA, morpholino subunits or 2'-O-methyl RNA. Thus Summerton provides motivation to increase the length of the 18-mer

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oligonucleotide taught by van Ommen et al. to generate a more efficient and target specific oligonucleotide.

Baker et al. teach antisense oligonucleotide molecules comprising conjugates such as polyethylene glycol chemically linked to the antisense oligonucleotide enhance the activity, cellular distribution and cellular uptake of the oligonucleotides (see 0094).

Hudziak et al. teach the use of morpholino antisense oligonucleotides to correct natural mRNA splice processing in methods of treating or preventing a disease state wherein the oligonucleotide contains a polyethylene glycol chain to enhance the solubility of the compound (see 0154). Hudziak et al. describes morpholino oligomers as oligonucleotides composed of morpholino subunits that lack a ribose backbone linked to a phosphodiester bond (see 0031).

It is well known in the prior art that morpholino antisense oligonucleotides are described as DNA analogs wherein the sequence of the morpholino antisense has thymine bases substituted for uracil bases (see Iverson et al, Table 1 on page 2511).

It would have been obvious for one of ordinary skill in the art to make a 25-mer morpholino oligonucleotide targeted to exon 53 wherein the oligonucleotide comprised the 18 nucleotides taught by van Ommen et al. van Ommen et al. teach inducing exon skipping in the DMD gene can restore dystrophin synthesis in up to 80% of treated cells, thereby providing methods of treatment for DMD. van Ommen et al. demonstrably teach targeting an exon internal region of exon 53 using an oligonucleotide having SEQ ID No. 29 induced exon skipping. This region targeted by the antisense oligonucleotide

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of van Ommen et al. is within the annealing site of the exon 53 target gene which SEQ ID No. 193 binds (see H53A(+23+47) and (+39+69) of the instant specification).

Given this finding by van Ommen et al. and the teaching of Summerton et al., one of skill in the art would have used the oligonucleotide taught by van Ommen et al., represented as SEQ ID No. 29, to make a 25-mer oligonucleotide comprising morpholino subunits to induce exon skipping of exon 53 more efficiently because a 25-mer and 28-mer morpholino oligonucleotide was shown by Summerton et al. to be more efficient than shorter oligonucleotides targeted to the same region.

It would have further been obvious to one of ordinary skill in the art to represent the morpholino antisense oligonucleotide using thymine bases instead of uracil bases because it was well known in the art that morpholino oligomers are DNA analog oligomers that do not have a ribose backbone, as taught by Hudziak et al. and therefore when annotating the sequence of the morpholino oligonucleotide, uracil bases would be substituted with thymine bases, as shown by Iversen et al.

One of ordinary skill in the art would have chemically linked a polyethylene glycol chain to the morpholino oligonucleotide to enhance the delivery and solubility of the oligonucleotide for use in methods of treatment as demonstrated by Hudziak et al. and Baker et al.

One of ordinary skill in the art would have expected to be capable of making a 25-mer antisense oligonucleotide with a reasonable expectation that this oligonucleotide would achieve both high efficacy and high specificity to the target region of exon 53 to induce exon skipping as shown by Summerton et al.

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Thus in the absence of evidence to the contrary, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 8-9 are provisionally rejected under the judicially created doctrine of double patenting over claims 2-5 of copending Application No. 14/273,379. This is a provisional double patenting rejection since the conflicting claims have not yet been patented. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of the patent are drawn to patently indistinguishable subject matter.

Claims 8-9 are provisionally rejected under the judicially created doctrine of double patenting over claims 21-49 of copending Application No. 14/086,859. Baker et al. teach antisense oligonucleotide molecules comprising conjugates such as

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polyethylene glycol chemically linked to the antisense oligonucleotide enhance the activity, cellular distribution and cellular uptake of the oligonucleotides (see 0094). Hudziak et al. teach the use of morpholino antisense oligonucleotides to correct natural mRNA splice processing in methods of treating or preventing a disease state wherein the oligonucleotide contains a polyethylene glycol chain to enhance the solubility of the compound (see 0154). Hudziak et al. describes morpholino oligomers as oligonucleotides composed of morpholino subunits that lack a ribose backbone linked to a phosphodiester bond (see 0031). One of ordinary skill in the art would have chemically linked a polyethylene glycol chain to the morpholino oligonucleotide to enhance the delivery and solubility of the oligonucleotide for use in methods of treatment as demonstrated by Hudziak et al. and Baker et al.

This is a provisional double patenting rejection since the conflicting claims have not yet been patented. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of the patent are drawn to patently indistinguishable subject matter.

Claims 8-9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36 of U.S. Patent No. 8,455,636. Baker et al. teach antisense oligonucleotide molecules comprising conjugates such as polyethylene glycol chemically linked to the antisense oligonucleotide enhance the activity, cellular distribution and cellular uptake of the oligonucleotides (see 0094).

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Hudziak et al. teach the use of morpholino antisense oligonucleotides to correct natural mRNA splice processing in methods of treating or preventing a disease state wherein the oligonucleotide contains a polyethylene glycol chain to enhance the solubility of the compound (see 0154). Hudziak et al. describes morpholino oligomers as oligonucleotides composed of morpholino subunits that lack a ribose backbone linked to a phosphodiester bond (see 0031). One of ordinary skill in the art would have chemically linked a polyethylene glycol chain to the morpholino oligonucleotide to enhance the delivery and solubility of the oligonucleotide for use in methods of treatment as demonstrated by Hudziak et al. and Baker et al.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of the patent are drawn to patently indistinguishable subject matter.

Claims 8-9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 8,232,384. Baker et al. teach antisense oligonucleotide molecules comprising conjugates such as polyethylene glycol chemically linked to the antisense oligonucleotide enhance the activity, cellular distribution and cellular uptake of the oligonucleotides (see 0094).

Hudziak et al. teach the use of morpholino antisense oligonucleotides to correct natural mRNA splice processing in methods of treating or preventing a disease state wherein the oligonucleotide contains a polyethylene glycol chain to enhance the solubility of the compound (see 0154). Hudziak et al. describes morpholino oligomers

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as oligonucleotides composed of morpholino subunits that lack a ribose backbone linked to a phosphodiester bond (see 0031). One of ordinary skill in the art would have chemically linked a polyethylene glycol chain to the morpholino oligonucleotide to enhance the delivery and solubility of the oligonucleotide for use in methods of treatment as demonstrated by Hudziak et al. and Baker et al.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of the patent are drawn to patently indistinguishable subject matter.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Kimberly Chong** whose telephone number is **571-272-3111**. The examiner can normally be reached Monday thru Friday between 9-5 pm.

If attempts to reach the examiner by telephone are unsuccessful please contact the SPE for 1674 Christopher Babic at 571-272-8507. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image

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problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Kimberly Chong/
Primary Examiner
Art Unit 1674



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

123147 7590 03/18/2015
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

EXAMINER	
CHONG, KIMBERLY	
ART UNIT	PAPER NUMBER

1674

DATE MAILED: 03/18/2015

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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14/317,952

06/27/2014

Stephen Donald WILTON

AVN-008CN27

2684

TITLE OF INVENTION: ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$480	\$0	\$0	\$480	06/18/2015

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL
#: 36537

Complete and send this form, together with applicable fee(s), to: **Mail** **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

123147 7590 03/18/2015
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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14/317,952 06/27/2014 Stephen Donald WILTON AVN-008CN27 2684

TITLE OF INVENTION: ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$480	\$0	\$0	\$480	06/18/2015

EXAMINER	ART UNIT	CLASS-SUBCLASS
CHONG, KIMBERLY	1674	536-024500

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

1 _____

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☐ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ Applicant certifying micro entity status. See 37 CFR 1.29
☐ Applicant asserting small entity status. See 37 CFR 1.27
☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/317,952	06/27/2014	Stephen Donald WILTON	AVN-008CN27	2684

EXAMINER
CHONG, KIMBERLY

ART UNIT	PAPER NUMBER
1674	

DATE MAILED: 03/18/2015

123147 7590 03/18/2015
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 14/317,952	Applicant(s) WILTON ET AL.	
	Examiner KIMBERLY CHONG	Art Unit 1674	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 02/06/2015.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☒ The allowed claim(s) is/are 4 and 5. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a) ☐ All b) ☐ Some *c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date <u>02/06/15, 03/06/15</u> 3. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material 4. <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date _____ .	5. <input type="checkbox"/> Examiner's Amendment/Comment 6. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance 7. <input type="checkbox"/> Other _____.
--	---

/KIMBERLY CHONG/
Primary Examiner, Art Unit 1674

Application/Control Number: 14/317,952
Art Unit: 1674

Page 2

The present application is being examined under the pre-AIA first to invent provisions.

The following is an examiner's statement of reasons for allowance: Applicant's remarks filed 02/06/2015 are sufficient to overcome the rejection of record because the cited references would not lead one of ordinary skill to increase the length of h53AON1 to arrive at the claimed oligonucleotide.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Kimberly Chong** whose telephone number is **571-272-3111**. The examiner can normally be reached Monday thru Friday between 9-5 pm.

If attempts to reach the examiner by telephone are unsuccessful please contact the SPE for 1674 Mark Shibuya at 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within

Application/Control Number: 14/317,952

Page 3

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5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

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/Kimberly Chong/
Primary Examiner
Art Unit 1674



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/317,952	06/27/2014	Stephen Donald WILTON	AVN-008CN27	2684
123147	7590	11/07/2014		
Nelson Mullins Riley & Scarborough LLP/Sarepta One Post Office Square Boston, MA 02109			EXAMINER CHONG, KIMBERLY	
			ART UNIT	PAPER NUMBER
			1674	
			NOTIFICATION DATE	DELIVERY MODE
			11/07/2014	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipboston.docketing@nelsonmullins.com
chris.schlauch@nelsonmullins.com
ipqualityassuranceboston@nelsonmullins.com

Application No.
14/317,952
#: 86544Applicant(s)
WILTON ET AL.**Office Action Summary**Examiner
KIMBERLY CHONGArt Unit
1674AIA (First Inventor to File)
Status
No**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08/22/2014.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 4 and 5 is/are pending in the application.
 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 4 and 5 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 06/27/2014 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
 Paper No(s)/Mail Date 8/22/14, 7/18/14.
- 3) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. ____.
- 4) ☐ Other: ____.

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The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

Status of the Application

Claims 4 and 5 are pending in the instant application.

Information Disclosure Statement

The submission of the Information Disclosure Statements on 08/22/2014 and 07/18/2014 is in compliance with 37 CFR 19.7. The information disclosure statements have been considered by the examiner and signed copies have been placed in the file.

Claim Rejections - 35 USC § 103

The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-5 are rejected under pre-AIA 35 U.S.C. 103(a) as being obvious over van Ommen (US Application 20060147952), Agrawal et al. (Antisense Research and Development 2:261-266, 1992), Matsuo et al. (US 6,653,467) and Monia et al. (US 6,391,636).

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under pre-AIA 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The claims are drawn to an antisense oligonucleotide of 25 nucleotides comprising at least 20 bases of SEQ ID No. 193, in which cytosine bases are 5-methyl-cytosine bases, wherein the antisense oligonucleotide is a 2'-O-methyl phosphorothioate oligoribonucleotide, wherein said oligonucleotide induces exon 53 skipping and a composition comprising said antisense oligonucleotide.

van Ommen teach an oligonucleotide having SEQ ID No. 29 that has 18 nucleotides identical to the claimed SEQ ID No. 193. van Ommen teach the oligonucleotide can comprise modified nucleotides such as 2'-O-methyl, modified phosphorothioate linkages, peptide nucleic acids and locked nucleic acids (see paragraph 0019). van Ommen teach in [0018] oligonucleotides that are complementary to a consecutive part of between 16 and 50 nucleotides of an exon RNA and teach different types of nucleic acid molecules can be used to generate the oligonucleotide.

van Ommen et al. do not exemplify an oligonucleotide having 25 nucleotides comprising 5-methyl-cytosine bases and 2'-O-methyl phosphorothioate as claimed.

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Agrawal et al. identified a target region of a gene and constructed oligonucleotides of 20, 24, 25 and 28 nucleotides in length having phosphorothioate backbones targeted to a specific region of an HIV gene (see Figure 1). Agrawal et al. found the oligonucleotides were capable of inhibiting viral gene expression wherein the 25 mer oligonucleotide was selected for further clinical studies. Agrawal et al. demonstrates the necessity of the skilled artisan to construct and test various sized oligonucleotides once a target region is identified.

Matsuo et al. teach a 31-mer oligonucleotide for use in exon skipping (see columns 10 and 11). Thus it was known in the prior art that antisense oligonucleotides longer than 18 nucleotides in length were capable of inducing exon skipping.

Monia et al. teach well known modifications of antisense oligonucleotides comprising modified backbones and nucleobases wherein preferred modifications being 2'-O-methyl phosphorothioate and 5-methyl-cytosine (see columns 7 and 8). Monia et al. teach such modification increase the stability of the oligonucleotide, particularly the preferred use of 5-methyl-cytosine which has been shown in "to increase nucleic acid duplex stability".

It would have been obvious for one of ordinary skill in the art to make a longer oligonucleotide targeted to exon 53, given van Ommen et al. demonstrably teach targeting an exon internal region of exon 53 induced exon skipping. One would have wanted to clearly make longer oligonucleotides around this target region to find the most efficient oligonucleotide for inducing exon skipping, particularly given the teachings of Agrawal et al. as well as Matsuo et al.

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Modifications of oligonucleotides to increase duplex stability and nuclease resistance was well known in the art and one of ordinary skill in the art would have been motivated to incorporate 2'-O-methyl phosphorothioate and 5-methyl-cytosine as these were preferred modifications as taught by Monia et al.

One of ordinary skill in the art would have expected to be capable of making these modifications, the steps of which are routine to the skilled artisan. Thus in the absence of evidence to the contrary, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 4-5 are provisionally rejected under the judicially created doctrine of double patenting over claim 1 of copending Application No. 14/273,379. This is a provisional double patenting rejection since the conflicting claims have not yet been patented. Although the conflicting claims are not identical, they are not patentably

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distinct from each other because the instant claims and the claims of the patent are drawn to patently indistinguishable subject matter.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Kimberly Chong** whose telephone number is **571-272-3111**. The examiner can normally be reached Monday thru Friday between 9-5 pm.

If attempts to reach the examiner by telephone are unsuccessful please contact the SPE for 1674 Christopher Babic at 571-272-8507. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

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/Kimberly Chong/
Primary Examiner
Art Unit 1674



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/523,610	10/24/2014	Peter SAZANI	AVN-009DV	9511

123147 7590 05/11/2016
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

EXAMINER

MCDONALD, JENNIFER SUE PITRAK

ART UNIT	PAPER NUMBER
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1674

NOTIFICATION DATE	DELIVERY MODE
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05/11/2016

ELECTRONIC

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The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipboston.docketing@nelsonmullins.com
chris.schlauch@nelsonmullins.com
ipqualityassuranceboston@nelsonmullins.com

Application No.
14/523,610
#: 98551Applicant(s)
SAZANI ET AL.**Office Action Summary**Examiner
JENNIFER PITRAK MCDONALDArt Unit
1674AIA (First Inventor to File)
Status
No**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
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Status

- 1) ☒ Responsive to communication(s) filed on 10/24/2014.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 1-65 is/are pending in the application.
 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☐ Claim(s) ____ is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☒ Claim(s) 1-65 are subject to restriction and/or election requirement.

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Application Papers

- 10) ☐ The specification is objected to by the Examiner.
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Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
 Paper No(s)/Mail Date ____.
- 3) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. ____.
- 4) ☐ Other: ____.

Application/Control Number: 14/523,610
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Page 2

The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 1-3, drawn to a composition for use in producing exon skipping of exon 44 in the processing of human dystrophin pre-processed mRNA, classified in C12N 15/111. Election of this group requires the further election of **species 1**.
2. Claims 4-7, drawn to a composition for use in producing exon skipping of exon 45 in the processing of human dystrophin pre-processed mRNA, classified in C12N 15/111. Election of this group requires the further election of **species 2**.
3. Claims 8-11, drawn to a composition for use in producing exon skipping of exon 46 in the processing of human dystrophin pre-processed mRNA, classified in C12N 15/111. Election of this group requires the further election of **species 3**.
4. Claims 12-15, drawn to a composition for use in producing exon skipping of exon 47 in the processing of human dystrophin pre-processed mRNA, classified in C12N 15/111. Election of this group requires the further election of **species 4**.
5. Claims 16-19, drawn to a composition for use in producing exon skipping of exon 48 in the processing of human dystrophin pre-processed mRNA, classified in C12N 15/111. Election of this group requires the further election of **species 5**.
6. Claims 20-23, drawn to a composition for use in producing exon skipping of exon 49 in the processing of human dystrophin pre-processed mRNA, classified in C12N 15/111. Election of this group requires the further election of **species 6**.
7. Claims 24-27, drawn to a composition for use in producing exon skipping of exon 50 in the processing of human dystrophin pre-processed mRNA, classified in C12N 15/111. Election of this group requires the further election of **species 7**.
8. Claims 28-31, drawn to a composition for use in producing exon skipping of exon 51 in the processing of human dystrophin pre-processed mRNA, classified in C12N 15/111. Election of this group requires the further election of **species 8**.

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9. Claims 32-35, drawn to a composition for use in producing exon skipping of exon 52 in the processing of human dystrophin pre-processed mRNA, classified in C12N 15/111. Election of this group requires the further election of **species 9**.
10. Claims 36-39, drawn to a composition for use in producing exon skipping of exon 53 in the processing of human dystrophin pre-processed mRNA, classified in C12N 15/111. Election of this group requires the further election of **species 10**.
11. Claims 40-43, drawn to a composition for use in producing exon skipping of exon 54 in the processing of human dystrophin pre-processed mRNA, classified in C12N 15/111. Election of this group requires the further election of **species 11**.
12. Claims 44-47, drawn to a composition for use in producing exon skipping of exon 55 in the processing of human dystrophin pre-processed mRNA, classified in C12N 15/111. Election of this group requires the further election of **species 12**.
13. Claim 51, drawn to a method of treating muscular dystrophy by administering an antisense compound targeted to exon 44 of a dystrophin gene, classified in C12N 2320/33. Election of this group requires the further election of **species 1**.
14. Claim 52, drawn to a method of treating muscular dystrophy by administering an antisense compound targeted to exon 45 of a dystrophin gene, classified in C12N 2320/33. Election of this group requires the further election of **species 2**.
15. Claim 53, drawn to a method of treating muscular dystrophy by administering an antisense compound targeted to exon 46 of a dystrophin gene, classified in C12N 2320/33. Election of this group requires the further election of **species 3**.
16. Claim 54, drawn to a method of treating muscular dystrophy by administering an antisense compound targeted to exon 47 of a dystrophin gene, classified in C12N 2320/33. Election of this group requires the further election of **species 4**.
17. Claim 55, drawn to a method of treating muscular dystrophy by administering an antisense compound targeted to exon 48 of a dystrophin gene, classified in C12N 2320/33. Election of this group requires the further election of **species 5**.
18. Claim 56, drawn to a method of treating muscular dystrophy by administering an antisense compound targeted to exon 49 of a dystrophin gene, classified in C12N 2320/33. Election of this group requires the further election of **species 6**.
19. Claims 57 and 63, drawn to a method of treating muscular dystrophy by administering an antisense compound targeted to exon 50 of a dystrophin gene, classified in C12N 2320/33. Election of this group requires the further election of **species 7**.

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20. Claim 58, drawn to a method of treating muscular dystrophy by administering an antisense compound targeted to exon 51 of a dystrophin gene, classified in C12N 2320/33. Election of this group requires the further election of **species 8**.
21. Claim 59, drawn to a method of treating muscular dystrophy by administering an antisense compound targeted to exon 52 of a dystrophin gene, classified in C12N 2320/33. Election of this group requires the further election of **species 9**.
22. Claim 60, drawn to a method of treating muscular dystrophy by administering an antisense compound targeted to exon 53 of a dystrophin gene, classified in C12N 2320/33. Election of this group requires the further election of **species 10**.
23. Claim 61, drawn to a method of treating muscular dystrophy by administering an antisense compound targeted to exon 54 of a dystrophin gene, classified in C12N 2320/33. Election of this group requires the further election of **species 11**.
24. Claim 62, drawn to a method of treating muscular dystrophy by administering an antisense compound targeted to exon 55 of a dystrophin gene, classified in C12N 2320/33. Election of this group requires the further election of **species 12**.

The inventions are distinct, each from the other because of the following reasons:

Each of Inventions 1-12 and each of Inventions 13-24 are related as product and process of use, respectively. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product(s) can be used to detect target nucleic acid molecules in a hybridization assay.

Inventions 1-12 are directed to related products. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have materially different designs and are

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Page 5

mutually exclusive. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions 13-24 are directed to related processes. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have materially different designs and are mutually exclusive. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Invention 1 and each of Inventions 14-24 are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the methods of Inventions 14-24 require an antisense oligonucleotide that is distinct from that of Invention 1.

Invention 2 and each of Inventions 13 and 15-24 are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the methods of Inventions 13 and 15-24 require an antisense oligonucleotide that is distinct from that of Invention 2.

Invention 3 and each of Inventions 13, 14, and 16-24 are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant

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case, the methods of Inventions 13, 14, and 16-24 require an antisense oligonucleotide that is distinct from that of Invention 3.

Invention 4 and each of Inventions 13-15 and 17-24 are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the methods of Inventions 13-15 and 17-24 require an antisense oligonucleotide that is distinct from that of Invention 4.

Invention 5 and each of Inventions 13-16 and 18-24 are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the methods of Inventions 13-16 and 18-24 require an antisense oligonucleotide that is distinct from that of Invention 5.

Invention 6 and each of Inventions 13-17 and 19-24 are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the methods of Inventions 13-17 and 19-24 require an antisense oligonucleotide that is distinct from that of Invention 6.

Invention 7 and each of Inventions 13-18 and 20-24 are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the methods of Inventions 13-18 and 20-24 require an antisense oligonucleotide that is distinct from that of Invention 7.

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Invention 8 and each of Inventions 13-19 and 21-24 are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the methods of Inventions 13-19 and 21-24 require an antisense oligonucleotide that is distinct from that of Invention 8.

Invention 9 and each of Inventions 13-20 and 22-24 are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the methods of Inventions 13-20 and 22-24 require an antisense oligonucleotide that is distinct from that of Invention 9.

Invention 10 and each of Inventions 13-21, 23, and 24 are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the methods of Inventions 13-21, 23, and 24 require an antisense oligonucleotide that is distinct from that of Invention 10.

Invention 11 and each of Inventions 13-22 and 24 are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the methods of Inventions 13-22 and 24 require an antisense oligonucleotide that is distinct from that of Invention 11.

Invention 12 and each of Inventions 13-23 are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot

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be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the methods of Inventions 13-23 require an antisense oligonucleotide that is distinct from that of Invention 12.

Claims 48-50, 64, and 65 link(s) inventions 13-24. The restriction requirement among the linked inventions is **subject to** the nonallowance of the linking claim(s), claims 48-50, 64, and 65. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Species 1

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Claim(s) 1 and 51 is/are generic to the following disclosed patentably distinct species:
SEQ ID NOs:1 and 3-20. The species are independent or distinct because each species has a distinct structure. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, or a single grouping of patentably indistinct species, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is a search and/or examination burden for the patentably distinct species as set forth above because at least the following reason(s) apply:

each species requires a distinct search and review of the results of the search.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or a grouping of patentably indistinct species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species or grouping of patentably indistinct species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under

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37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species or grouping of patentably indistinct species.

Should applicant traverse on the ground that the species, or groupings of patentably indistinct species from which election is required, are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing them to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Species 2

Claim(s) 4 and 52 is/are generic to the following disclosed patentably distinct species: SEQ ID NOs: 21-76 and 612-624. The species are independent or distinct because each species has a distinct structure. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, or a single grouping of patentably indistinct species, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is a search and/or examination burden for the patentably distinct species as set forth above because at least the following reason(s) apply:

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each species requires a distinct search and review of the results of the search.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or a grouping of patentably indistinct species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species or grouping of patentably indistinct species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species or grouping of patentably indistinct species.

Should applicant traverse on the ground that the species, or groupings of patentably indistinct species from which election is required, are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing them to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Species 3

Claim(s) 8 and 53 is/are generic to the following disclosed patentably distinct species: SEQ ID NOs:77-125. The species are independent or distinct because each species has a distinct structure. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, or a single grouping of patentably indistinct species, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is a search and/or examination burden for the patentably distinct species as set forth above because at least the following reason(s) apply:

each species requires a distinct search and review of the results of the search.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or a grouping of patentably indistinct species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species or grouping of patentably indistinct species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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The election may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species or grouping of patentably indistinct species.

Should applicant traverse on the ground that the species, or groupings of patentably indistinct species from which election is required, are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing them to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Species 4

Claim(s) 12 and 54 is/are generic to the following disclosed patentably distinct species: SEQ ID NOs:126-169. The species are independent or distinct because each species has a distinct structure. In addition, these species are not obvious variants of each other based on the current record.

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, or a single grouping of patentably indistinct species, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is a search and/or examination burden for the patentably distinct species as set forth above because at least the following reason(s) apply:

each species requires a distinct search and review of the results of the search.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or a grouping of patentably indistinct species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species or grouping of patentably indistinct species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species or grouping of patentably indistinct species.

Should applicant traverse on the ground that the species, or groupings of patentably indistinct species from which election is required, are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing them to be obvious variants or

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clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Species 5

Claim(s) 16 and 55 is/are generic to the following disclosed patentably distinct species: SEQ ID NOs:170-224 and 634. The species are independent or distinct because each species has a distinct structure. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, or a single grouping of patentably indistinct species, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is a search and/or examination burden for the patentably distinct species as set forth above because at least the following reason(s) apply:

each species requires a distinct search and review of the results of the search.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or a grouping of patentably indistinct species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species or grouping of patentably indistinct species,

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including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species or grouping of patentably indistinct species.

Should applicant traverse on the ground that the species, or groupings of patentably indistinct species from which election is required, are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing them to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Species 6

Claim(s) 20 and 56 is/are generic to the following disclosed patentably distinct species:
SEQ ID NOs:225-266. The species are independent or distinct because each species has a

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distinct structure. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, or a single grouping of patentably indistinct species, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is a search and/or examination burden for the patentably distinct species as set forth above because at least the following reason(s) apply:

each species requires a distinct search and review of the results of the search.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or a grouping of patentably indistinct species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species or grouping of patentably indistinct species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species or grouping of patentably indistinct species.

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Should applicant traverse on the ground that the species, or groupings of patentably indistinct species from which election is required, are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing them to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Species 7

Claim(s) 24 and 57 is/are generic to the following disclosed patentably distinct species: SEQ ID NOs: 267-286 and 288-308. The species are independent or distinct because each species has a distinct structure. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, or a single grouping of patentably indistinct species, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is a search and/or examination burden for the patentably distinct species as set forth above because at least the following reason(s) apply:

each species requires a distinct search and review of the results of the search.

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Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or a grouping of patentably indistinct species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species or grouping of patentably indistinct species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species or grouping of patentably indistinct species.

Should applicant traverse on the ground that the species, or groupings of patentably indistinct species from which election is required, are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing them to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

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Species 8

Claim(s) 28 and 58 is/are generic to the following disclosed patentably distinct species: SEQ ID NOs: 309-371. The species are independent or distinct because each species has a distinct structure. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, or a single grouping of patentably indistinct species, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is a search and/or examination burden for the patentably distinct species as set forth above because at least the following reason(s) apply:

each species requires a distinct search and review of the results of the search.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or a grouping of patentably indistinct species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species or grouping of patentably indistinct species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered

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timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species or grouping of patentably indistinct species.

Should applicant traverse on the ground that the species, or groupings of patentably indistinct species from which election is required, are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing them to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Species 9

Claim(s) 32 and 59 is/are generic to the following disclosed patentably distinct species: SEQ ID NOs: 372-415. The species are independent or distinct because each species has a distinct structure. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, or a single grouping of patentably indistinct species, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

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There is a search and/or examination burden for the patentably distinct species as set forth above because at least the following reason(s) apply:

each species requires a distinct search and review of the results of the search.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or a grouping of patentably indistinct species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species or grouping of patentably indistinct species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species or grouping of patentably indistinct species.

Should applicant traverse on the ground that the species, or groupings of patentably indistinct species from which election is required, are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing them to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Species 10

Claim(s) 36 and 60 is/are generic to the following disclosed patentably distinct species: SEQ ID NOs: 416-475 and 625-633. The species are independent or distinct because each species has a distinct structure. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, or a single grouping of patentably indistinct species, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is a search and/or examination burden for the patentably distinct species as set forth above because at least the following reason(s) apply:

each species requires a distinct search and review of the results of the search.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or a grouping of patentably indistinct species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species or grouping of patentably indistinct species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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The election may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species or grouping of patentably indistinct species.

Should applicant traverse on the ground that the species, or groupings of patentably indistinct species from which election is required, are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing them to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Species 11

Claim(s) 40 and 61 is/are generic to the following disclosed patentably distinct species:
SEQ ID NOs: 476-519. The species are independent or distinct because each species has a distinct structure. In addition, these species are not obvious variants of each other based on the current record.

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, or a single grouping of patentably indistinct species, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is a search and/or examination burden for the patentably distinct species as set forth above because at least the following reason(s) apply:

each species requires a distinct search and review of the results of the search.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or a grouping of patentably indistinct species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species or grouping of patentably indistinct species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species or grouping of patentably indistinct species.

Should applicant traverse on the ground that the species, or groupings of patentably indistinct species from which election is required, are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing them to be obvious variants or

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clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Species 12

Claim(s) 44 and 62 is/are generic to the following disclosed patentably distinct species: SEQ ID NOs: 520-569 and 635. The species are independent or distinct because each species has a distinct structure. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, or a single grouping of patentably indistinct species, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is a search and/or examination burden for the patentably distinct species as set forth above because at least the following reason(s) apply:

each species requires a distinct search and review of the results of the search.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or a grouping of patentably indistinct species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species or grouping of patentably indistinct species,

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including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species or grouping of patentably indistinct species.

Should applicant traverse on the ground that the species, or groupings of patentably indistinct species from which election is required, are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing them to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Application/Control Number: 14/523,610
Art Unit: 1674

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER PITRAK MCDONALD whose telephone number is (571)270-3061. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia (Anna) Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JENNIFER PITRAK MCDONALD/
Primary Examiner, Art Unit 1674



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

123147 7590 11/14/2016
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

EXAMINER	
CHONG, KIMBERLY	
ART UNIT	PAPER NUMBER

1674

DATE MAILED: 11/14/2016

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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14/740,097

06/15/2015

Stephen Donald Wilton

AVN-008CN28

6495

TITLE OF INVENTION: ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$480	\$0	\$0	\$480	02/14/2017

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL
#: 36581

Complete and send this form, together with applicable fee(s), to: **Mail** **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

123147 7590 11/14/2016
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/740,097	06/15/2015	Stephen Donald Wilton	AVN-008CN28	6495

TITLE OF INVENTION: ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$480	\$0	\$0	\$480	02/14/2017

EXAMINER	ART UNIT	CLASS-SUBCLASS
CHONG, KIMBERLY	1674	536-024500

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

1 _____

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☐ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ Applicant certifying micro entity status. See 37 CFR 1.29
☐ Applicant asserting small entity status. See 37 CFR 1.27
☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/740,097	06/15/2015	Stephen Donald Wilton	AVN-008CN28	6495

EXAMINER
CHONG, KIMBERLY

ART UNIT	PAPER NUMBER
1674	

DATE MAILED: 11/14/2016

123147 7590 11/14/2016
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 14/740,097	Applicant(s) WILTON ET AL.	
	Examiner KIMBERLY CHONG	Art Unit 1674	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 10/07/2016.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are 2-15. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a) ☐ All b) ☐ Some *c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date <u>10/07/2016</u> 3. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material 4. <input type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date _____ .	5. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 6. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance 7. <input type="checkbox"/> Other _____.
---	--

/KIMBERLY CHONG/ Primary Examiner, Art Unit 1674	
---	--

Application/Control Number: 14/740,097
Art Unit: 1674

Page 2

The present application is being examined under the pre-AIA first to invent provisions.

The following is an examiner's statement of reasons for allowance: the Terminal Disclaimer filed 10/07/2016 has been approved and overcomes the rejections of record. All claims are in condition for allowance.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Kimberly Chong** whose telephone number is **571-272-3111**. The examiner can normally be reached Monday thru Friday between 9-5 pm.

If attempts to reach the examiner by telephone are unsuccessful please contact the SPE for 1674 Shaojia Anna Jiang at 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It

Application/Control Number: 14/740,097

Page 3

Art Unit: 1674

also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Kimberly Chong/
Primary Examiner
Art Unit 1674



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/740,097	06/15/2015	Stephen Donald Wilton	AVN-008CN28	6495

123147 7590 04/08/2016
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

EXAMINER

CHONG, KIMBERLY

ART UNIT	PAPER NUMBER
----------	--------------

1674

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

04/08/2016

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipboston.docketing@nelsonmullins.com
chris.schlauch@nelsonmullins.com
ipqualityassuranceboston@nelsonmullins.com

Application No.
14/740,097
#: 38588Applicant(s)
WILTON ET AL.**Office Action Summary**Examiner
KIMBERLY CHONGArt Unit
1674AIA (First Inventor to File)
Status
No**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03/07/2016.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 2-15 is/are pending in the application.
 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 2-15 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 06/15/2015 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☒ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 11/570,691.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
 Paper No(s)/Mail Date 03/7/16,9/15/15,9/14/15.
- 3) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. ____.
- 4) ☐ Other: ____.

Application/Control Number: 14/740,097
Art Unit: 1674

Page 2

The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of SEQ ID No. 3 in the reply filed on 03/07/2016 is acknowledged.

Status of the Application

Claims 2-15 are pending and are currently under examination.

Information Disclosure Statement

The submission of the Information Disclosure Statements on 03/07/2016 and 09/14/2015 and 09/15/2015 is in compliance with 37 CFR 1.97. The information disclosure statements have been considered by the examiner and signed copies have been placed in the file.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

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patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2-15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 9,249,416. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of the patent are drawn to patently indistinguishable subject matter.

The instant claims are drawn to a method of treatment of DMD using an antisense targeted to exon 8 and having SEQ ID Nos. 1, 2, 3, or 4. Patent '416 is drawn to antisense oligonucleotides having SEQ ID Nos. 1 and 2 and thus it would have been obvious to use the oligonucleotides of Patent '416 in the instant methods.

Applicants are encouraged to file an eTerminal Disclaimer in EFS-Web

The United States Patent and Trademark Office is pleased to announce the release of eTerminal Disclaimer in EFS-Web. The new eTerminal Disclaimer provides applicants with many advantages and promotes greater efficiency in the patent examination process. This web-based eTerminal Disclaimer can be filled out completely online through web-screens and no EFS-Web fillable forms are required. eTerminal Disclaimers are auto-processed and approved immediately upon submission if the request meets all of the requirements.

Fees must be paid immediately which will then provide users more financial flexibility. A paper terminal disclaimer filing requires a fee but does not guarantee a terminal disclaimer approval. Each eTerminal Disclaimer filed requires a single terminal disclaimer fee, but can include up to 50 "reference applications" and 50 "prior patents."

Basic Guidelines for Filing eTerminal Disclaimers:

- Must be able to access EFS-Web registered.

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- Registered eFiler users are strongly advised to transmit their electronic filings sufficiently early in the day to allow time for alternative paper filing when transmission cannot be initiated or correctly completed.
- The ability to submit an eTerminal Disclaimer under EFS-Web Contingency is not permitted.
- Consult the current fee schedule available at <http://www.uspto.gov/about/offices/cfo/finance/fees.jsp> for the correct fee amount. The fee required to be paid upon filing a request for eTerminal Disclaimer is: Statutory disclaimer, including terminal disclaimer.
- eTerminal Disclaimers via EFS-Web are accepted only for nonprovisional utility applications (including national stage and reissue) and Design applications (including reissue).
- Requests for terminal disclaimers for plant applications, reexaminations and terminal disclaimers based on a joint research agreement must be filed by paper. For assistance with filing an eTerminal Disclaimer, or to suggest improvements, please call the Patent Electronic Business Center at 866-217-9197 (toll free) or send an email to **EBC@uspto.gov**

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Kimberly Chong** whose telephone number is **571-272-3111**. The examiner can normally be reached Monday thru Friday between 9-5 pm.

If attempts to reach the examiner by telephone are unsuccessful please contact the SPE for 1674 Shaojia Anna Jiang at 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has

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been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Kimberly Chong/
Primary Examiner
Art Unit 1674



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/740,097	06/15/2015	Stephen Donald Wilton	AVN-008CN28	6495

123147 7590 11/06/2015
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

EXAMINER

CHONG, KIMBERLY

ART UNIT	PAPER NUMBER
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1674

NOTIFICATION DATE	DELIVERY MODE
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11/06/2015

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipboston.docketing@nelsonmullins.com
chris.schlauch@nelsonmullins.com
ipqualityassuranceboston@nelsonmullins.com

Application No.
14/740,097
#: 58594Applicant(s)
WILTON ET AL.**Office Action Summary**Examiner
KIMBERLY CHONGArt Unit
1674AIA (First Inventor to File)
Status
No**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06/15/2015.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 1 is/are pending in the application.
 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☐ Claim(s) ____ is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☒ Claim(s) 1 are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
 Paper No(s)/Mail Date ____.
- 3) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date ____.
- 4) ☐ Other: ____.

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The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

The claims are drawn to an antisense molecule capable of binding to a selected target site to induce exon skipping in the dystrophin gene as set forth in SEQ ID Nos. 1 to 202.

This invention is subject to a restriction of nucleic acid sequences.

Claim 1 specifically claims 202 different nucleic acid sequences. Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the different SEQ ID Nos. encompassed by claim 1 is subject to restriction. In the instant case, **one (1)** independent and distinct SEQ ID No. will be examined in a single application without restriction. Those sequences which are patentably indistinct from the sequence or region selected by the applicant will also be examined.

Claim 1 specifically embraces different antisense sequences with different SEQ ID Nos. Each of these nucleic acid molecules is considered to be structurally independent because each is represented by a unique sequence or structure. Furthermore, a search of all the sequences claimed presents an undue burden on the Patent and Trademark Office to search and examine because a search for one

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sequence will not necessarily reveal art for a different sequence. In view of the foregoing, applicants are required to elect up to **ONE (1) SEQ ID No.**

This is not a species election.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement

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may be traversed (37 CFR 1.143) and (ii) **identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Page 5

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Kimberly Chong** whose telephone number is **571-272-3111**. The examiner can normally be reached Monday thru Friday between 9-5 pm.

If attempts to reach the examiner by telephone are unsuccessful please contact the SPE for 1674 Mark Shibuya at 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Kimberly Chong/
Primary Examiner
Art Unit 1674



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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/743,856	06/18/2015	Richard K. Bestwick	AVN-010PCCN	1570

123147 7590 08/01/2016
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

EXAMINER

BOWMAN, AMY HUDSON

ART UNIT	PAPER NUMBER
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1674

NOTIFICATION DATE	DELIVERY MODE
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08/01/2016

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipboston.docketing@nelsonmullins.com
chris.schlauch@nelsonmullins.com
ipqualityassuranceboston@nelsonmullins.com

Application No.
14/743,856
#: 86690Applicant(s)
BESTWICK ET AL.**Office Action Summary**Examiner
AMY BOWMANArt Unit
1674AIA (First Inventor to File)
Status
No**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/18/15.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 1-28 is/are pending in the application.
 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☐ Claim(s) ____ is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
 Paper No(s)/Mail Date ____.
- 3) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. ____.
- 4) ☐ Other: ____.

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Art Unit: 1674

Page 2

The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-24, 27, and 28, drawn to an isolated antisense oligonucleotide, classified in C12N 15/113.

II. Claim 25, drawn to a method of treating Duchenne muscular dystrophy, classified in A61K 48/00.

III. Claim 26, drawn to a method for the manufacture of a medicament, classified in C12N 2310/11.

The inventions are distinct, each from the other because of the following reasons:

Inventions of groups II and III are related to the invention of group I as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product can be used as a size marker on a gel. The method can be practiced with an antibody or aptamer. To search for one would not necessarily return art against the other.

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Page 3

Inventions of groups II and III are directed to related methods. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a materially different design, mode of operation, function, and effect. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants. Each of the methods requires search and examination of different steps. To search for one of the methods would not necessarily return art against the other and therefore a search burden exists.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and/or examination burden if restriction were not required.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly

Application/Control Number: 14/743,856
Art Unit: 1674

Page 4

and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 or pre-AIA 35 U.S.C. 103(a) of the other invention.

This application contains claims directed to the following patentably distinct species:

Claim 12: methyl phosphonates, methyl phosphorothioates, phosphormorpholidates, phosphoropiperazidates, or phosphoroamidates.

Claims 1, 10, and 11 are generic.

The species are independent or distinct because each of the modifications has a different structure to be searched. In addition, these species are not obvious variants of each other based on the current record.

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, or a single grouping of patentably indistinct species, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species or grouping of patentably indistinct species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species or grouping of patentably indistinct species.

Should applicant traverse on the ground that the species, or groupings of patentably indistinct species from which election is required, are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing them to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the

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Art Unit: 1674

Page 6

evidence or admission may be used in a rejection under 35 U.S.C. 103 or pre-AIA 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be corrected in compliance with 37 CFR 1.48(a) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. A request to correct inventorship under 37 CFR 1.48(a) must be accompanied by an application data sheet in accordance with 37 CFR 1.76 that identifies each inventor by his or her legal name and by the processing fee required under 37 CFR 1.17(i).

The examiner has required restriction between product or apparatus claims and process claims. Where applicant elects claims directed to the product/apparatus, and all product/apparatus claims are subsequently found allowable, withdrawn process claims that include all the limitations of the allowable product/apparatus claims should be considered for rejoinder. All claims directed to a nonelected process invention must include all the limitations of an allowable product/apparatus claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product/apparatus claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37

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Page 7

CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product/apparatus are found allowable, an otherwise proper restriction requirement between product/apparatus claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product/apparatus claim will not be rejoined. See MPEP § 821.04.

Additionally, in order for rejoinder to occur, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product/apparatus claims. **Failure to do so may result in no rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMY BOWMAN whose telephone number is (571)272-0755. The examiner can normally be reached on Monday-Thursday 8:00 - 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMY BOWMAN
Primary Examiner
Art Unit 1674

/AMY BOWMAN/
Primary Examiner, Art Unit 1674



UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/776,533	09/14/2015	Richard K. BESTWICK	AVN-017CPUS	2035

123147 7590 02/28/2017
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

EXAMINER

SHIN, DANA H

ART UNIT	PAPER NUMBER
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1674

NOTIFICATION DATE	DELIVERY MODE
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02/28/2017

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipboston.docketing@nelsonmullins.com
chris.schlauch@nelsonmullins.com
ipqualityassuranceboston@nelsonmullins.com

Application No.
14/776,533
#: 58609Applicant(s)
BESTWICK ET AL.**Office Action Summary**Examiner
DANA SHINArt Unit
1674AIA (First Inventor to File)
Status
No**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2-3-2017.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 16 and 17 is/are pending in the application.
 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 16 and 17 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 9-14-2015 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
 Paper No(s)/Mail Date ____.
- 3) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date ____.
- 4) ☐ Other: ____.

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DETAILED ACTION

The present application is being examined under the pre-AIA first to invent provisions.

Election/Restrictions

Applicant's election without traverse of claims 1-17 with species election of SEQ ID NO:1 in the reply filed on February 3, 2017 is acknowledged.

Status of Claims

Claims 16-17 are currently pending and under examination on the merits in the instant case.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of pre-AIA 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

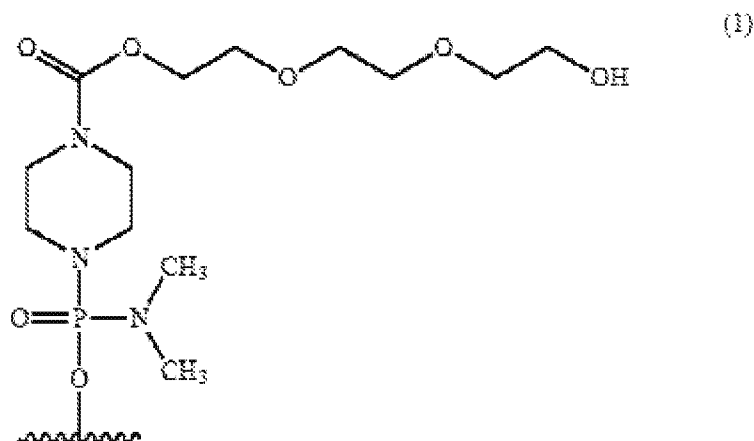
Claims 16-17 are rejected under pre-AIA 35 U.S.C. 102(e) as being anticipated by Watanabe et al. (US 2013/0211062 A1, applicant's citation).

Watanabe discloses SEQ ID NO:57 (5'-GUUGCCUCCGGUUCUGAAGGUGUUC), wherein SEQ ID NO:57 is modified with 2'-O-MOE phosphorothioates. See paragraph 0286 and Table 7.

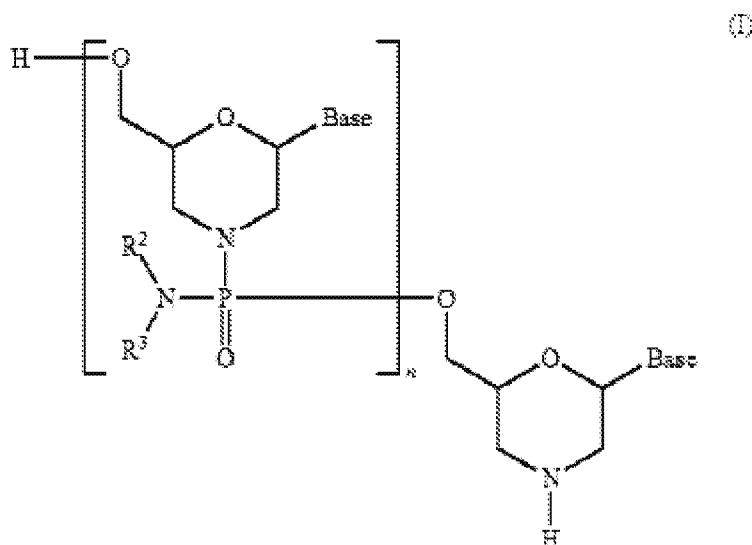
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Watanabe teaches that exon skipping oligonucleotides can have PMO, wherein the 5' end has the following structure "Group (1)" disclosed in paragraph 0162 as below:



Watanabe teaches that the PMO oligonucleotide has formula (I), wherein R² and R³ are same and represent alkyl. See paragraphs 0097 and 0103. See formula (I) as below:



Watanabe teaches that exon skipping oligonucleotides can be formulated as a pharmaceutical composition. See paragraphs 0164-0166.

It is noted that the nucleobase structures "A", "C", "G", and "T" recited in the "wherein" clause of the claims are merely art-recognized nucleobase structures, which are not novel, inventive structures, absent evidence to the contrary.

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Accordingly, all claim limitations are taught by Watanabe et al.

Claim Rejections - 35 USC § 103

The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under pre-AIA 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of pre-AIA 35 U.S.C. 103(c) and potential pre-AIA 35 U.S.C. 102(e), (f) or (g) prior art under pre-AIA 35 U.S.C. 103(a).

Claims 16-17 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Watanabe et al. (US 2013/0211062 A1, applicant's citation).

Watanabe teaches making an exon skipping PMO oligonucleotide of formula (I), wherein the 5' end has the structure of "Group (1)", wherein the structures of Watanabe's formula (I) and Group (1) correspond to the instantly claimed oligonucleotide structure. See paragraphs 0097, 0103, 0162.

Watanabe exemplifies SEQ ID NO:57 (5'-GUUGCCUCCGGUUCUGAAGGUGUUC), which is modified with 2'-O-MOE phosphorothioates. See paragraph 0286 and Table 7.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to replace 2'-O-MOE phosphorothioates in SEQ ID NO:57 with formula (I) and to added Group (1) with a reasonable expectation of success because Watanabe expressly taught making a PMO oligonucleotide having formula (I) and Group (1) when making exon skipping oligonucleotides, and because SEQ ID NO:57 was one of identified DMD exon 53 skipping oligonucleotides disclosed by Watanabe.

Accordingly, claims 16-17 taken as a whole would have been *prima facie* obvious at the time of the invention.

Claims 16-17 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Popplewell et al. (US 2010/0168212 A1, applicant's citation) in view of Watanabe et al. (US 2013/0211062 A1, applicant's citation).

Popplewell teaches making a PMO oligonucleotide comprising at least 25 nucleotides of SEQ ID NO:22 (5'-CTGTTGCCTCCGGTTCTGAAGGTGTTCTTG). See paragraphs 0011, 0015, and 0055. Hence, Popplewell inherently teaches making a 25-mer PMO oligonucleotide consisting of 5'-GTTGCCTCCGGTTCTGAAGGTGTTC, which is one of only 6 possible 25-mers within SEQ ID NO:22.

Popplewell does not teach that the PMO oligonucleotide has the chemical structure claimed in the instant case.

Watanabe teaches making a PMO oligonucleotide of formula (I), wherein the 5' end has the structure of "Group (1)", wherein the structures of Watanabe's formula (I) and Group (1) correspond to the instantly claimed oligonucleotide structure. See paragraphs 0097, 0103, 0162.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate Watanabe's PMO oligonucleotide structure into Popplewell's 25-mer

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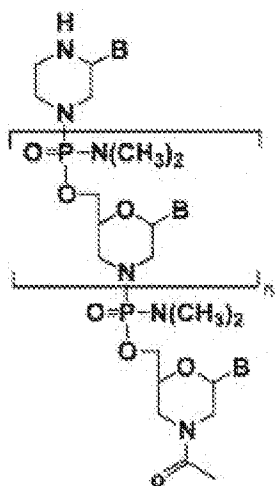
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within SEQ ID NO:22. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success because Watanabe's PMO oligonucleotide structure and synthesis methodologies were known to be useful when making exon skipping oligonucleotides. Further, the 25-mer nucleotide sequence of the instantly claimed oligonucleotide is inherently taught by Popplewell, who expressly taught making a 25-mer oligonucleotide within SEQ ID NO:22, which provides only 6 possible 25-mer oligonucleotides including the instantly claimed sequence. Accordingly, claims 16-17 taken as a whole would have been *prima facie* obvious at the time of the invention.

Claims 16-17 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Sazani et al. (US 2013/0190390 A1) in view of Watanabe et al. (US 2013/0211062 A1, applicant's citation).

Sazani discloses SEQ ID NO:631 (5'-TGTTGCCTCCGGTTCTGAAGGTGTTCTTGT) comprising the instantly claimed nucleotide sequence and teaches making an oligonucleotide of 20-35 PMO units. See page 44; paragraphs 0025, 0051.

Sazani teaches that the PMO backbone of the oligonucleotide can have the structure in Figure 1A as below:



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Sazani teaches making a pharmaceutical formulation containing the PMO oligonucleotide and a pharmaceutically acceptable carrier. See paragraph 0183.

Sazani teaches incorporating a 5' end structure into the above PMO oligonucleotide structure. See Figure 1B.

Sazani does not teach that the PMO oligonucleotide has the 5'-end structure claimed in the instant case.

Watanabe teaches making a PMO oligonucleotide, wherein the 5' end has the structure of "Group (1)", which corresponds to the instantly claimed 5' end structure. See paragraph 0162.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate Watanabe's 5' end structure into Sazani's 25-mer designed to comprise 25 nucleotides of SEQ ID NO:631, wherein the designed 25-mer is identical to the instantly claimed nucleotide sequence, which is one of a finite number of possible 25-mer PMO oligonucleotide sequences within SEQ ID NO:631. One of ordinary skill in the art would have been motivated to replace the 5' end structure in Figure 1B with Watanabe's "Group (1)" structure with a reasonable expectation of success because Watanabe's "Group (1)" is a functional equivalent of Sazani's 5' end structure in Figure 1B as both 5' end structures are carrier/delivery moieties. Accordingly, claims 16-17 taken as a whole would have been *prima facie* obvious at the time of the invention.

Claims 16-17 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Wilton et al. (US 9,024,007 B2, applicant's citation) in view of Watanabe et al. (US 2013/0211062 A1, applicant's citation).

Wilton's '007 patent claims the following:

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1. An antisense oligonucleotide of 25 bases comprising a base sequence that is 100% complementary to 25 consecutive nucleotides of a target region of exon 53 of the human dystrophin pre-mRNA, wherein the target region is within annealing site H53A(+23+47) and annealing site H53A(+39+69), wherein the antisense oligonucleotide base sequence comprises at least 20 consecutive bases of CAUUCAA CUG UUG CCU CCG GUU CUG AAG GUG (SEQ ID NO: 193), in which uracil bases are thymine bases, wherein the antisense oligonucleotide is a morpholino antisense oligonucleotide, wherein the antisense oligonucleotide is chemically linked to a polyethylene glycol chain, and wherein the antisense oligonucleotide specifically hybridizes to the target region to induce exon 53 skipping.

2. A pharmaceutical composition comprising an antisense oligonucleotide of 25 bases comprising a base sequence that is 100% complementary to 25 consecutive nucleotides of a target region of exon 53 of the human dystrophin pre-mRNA, wherein the target region is within annealing site H53A(+23+47) and annealing site H53A(+39+69), wherein the antisense oligonucleotide base sequence comprises at least 20 consecutive bases of CAUUCAA CUG UUG CCU CCG GUU CUG AAG GUG (SEQ ID NO: 193), in which uracil bases are thymine bases, wherein the antisense oligonucleotide is a morpholino antisense oligonucleotide, wherein the antisense oligonucleotide is chemically linked to a polyethylene glycol chain, and wherein the antisense oligonucleotide specifically hybridizes to the target region to induce exon 53 skipping, and a pharmaceutically acceptable carrier.

Hence, Wilton's '007 patent claims are drawn to a 25-mer PMO oligonucleotide having 22-mer 5'-GUUGCCUCCGGUUCUGAAGGUG of SEQ ID NO:193, which thus renders obvious the instantly claimed 25-mer PMO oligonucleotide sequence.

Wilton does not teach the PMO oligonucleotide has the chemical structure claimed in the instant case.

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Watanabe teaches making a PMO oligonucleotide of formula (I), wherein the 5' end has the structure of “Group (1)”, wherein the structures of Watanabe’s formula (I) and Group (1) correspond to the instantly claimed oligonucleotide structure. See paragraphs 0097, 0103, 0162.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate Watanabe’s PMO oligonucleotide structure into Wilton’s 25-mer that reads on the claimed invention in the ‘007 patent as well as the instantly claimed nucleotide sequence. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success because Watanabe’s PMO oligonucleotide structure and synthesis methodologies were known to be useful when making exon skipping oligonucleotides. Further, the 25-mer nucleotide sequence of the instantly claimed oligonucleotide is inherently rendered obvious by Wilton’s claims, which are directed a 25-mer PMO oligonucleotide having at least 20 of SEQ ID NO:193. Accordingly, claims 16-17 taken as a whole would have been *prima facie* obvious at the time of the invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van*

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Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP §§ 706.02(l)(1) - 706.02(l)(3) for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 16-17 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-2, 5-35, 39, and 42 of copending Application No. 15/417,401. Although the conflicting claims are not identical they are not patentably distinct from each other because the instant claims are encompassed and rendered obvious by the '401 claims that read on a PMO antisense oligonucleotide of the 25-mer sequence that is identical to the instantly claimed PMO nucleotide sequence as evidenced by the fact that the oligonucleotides of 20-50 nucleotides

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in length comprising at least 10 nucleotides of SEQ ID NO:1 encompass the instantly claimed 25-mer sequence. Note that SEQ ID NO:1 of the '401 claims comprise the entire 25-mer claimed in the instant case. In addition, note that the oligonucleotide of the '401 claims reads on the structure claimed in the instant case as evidenced by the disclosure of the '401 application that describes that the claimed “embodiment of the invention” has the structure of Figure 1B of the '401 application. Note that “those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent.” See MPEP §804. See also *Pfizer Inc. v. Teva Pharmaceuticals USA Inc.*, 518 F.3d 1353, 86 USPQ2d 1001 (Fed. Cir. 2008), wherein the court expressed the following: “To the extent that Pfizer contends that we may not rely on the teachings of the specification or claims in the '165 patent to reject the claims of the '068 patent, we disagree. See *Geneva*, 349 F.3d at 1386. There is nothing that prevents us from looking to the specification to determine the proper scope of the claims.”

Claims 16-17 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-22, 24, and 27 of copending Application No. 15/420,823. Although the conflicting claims are not identical they are not patentably distinct from each other because the instant claims are encompassed and rendered obvious by the '823 claims that read on a PMO antisense oligonucleotide of the 25-mer sequence that is identical to the instantly claimed PMO nucleotide sequence as evidenced by the fact that the oligonucleotides of 20-50 nucleotides in length comprising at least 20 nucleotides of SEQ ID NO:1 encompass the instantly claimed 25-mer sequence. Note that SEQ ID NO:1 of the '823 claims comprise the entire 25-mer claimed in the instant case. In addition, note that the oligonucleotide of the '823 claims reads on the structure claimed in the instant case as evidenced by the disclosure of the '823 application that

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describes that the claimed “embodiment of the invention” has the structure of Figure 1B of the ‘823 application. Note that “those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent.” See MPEP §804. See also *Pfizer Inc. v. Teva Pharmaceuticals USA Inc.*, 518 F3d 1353, 86 USPQ2d 1001 (Fed. Cir. 2008), wherein the court expressed the following: “To the extent that Pfizer contends that we may not rely on the teachings of the specification or claims in the ‘165 patent to reject the claims of the ‘068 patent, we disagree. *See Geneva*, 349 F.3d at 1386. There is nothing that prevents us from looking to the specification to determine the proper scope of the claims.”

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANA SHIN whose telephone number is (571)272-8008. The examiner can normally be reached on Monday through Thursday, 8am-6:30pm EST.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin
Primary Examiner
Art Unit 1674

/DANA SHIN/
Primary Examiner, Art Unit 1674



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/776,533	09/14/2015	Richard K. BESTWICK	AVN-017CPUS	2035

123147 7590 08/03/2016
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

EXAMINER

SHIN, DANA H

ART UNIT	PAPER NUMBER
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1674

NOTIFICATION DATE	DELIVERY MODE
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08/03/2016

ELECTRONIC

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ipboston.docketing@nelsonmullins.com
chris.schlauch@nelsonmullins.com
ipqualityassuranceboston@nelsonmullins.com

Application No.
14/776,533
#: 86623Applicant(s)
BESTWICK ET AL.**Office Action Summary**Examiner
DANA SHINArt Unit
1674AIA (First Inventor to File)
Status
No**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

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Status

- 1) ☒ Responsive to communication(s) filed on 2-29-2016.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 1-20 is/are pending in the application.
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- 7) ☐ Claim(s) ____ is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
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Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

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- 4) ☐ Other: ____.

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DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-17, drawn to an antisense oligonucleotide compound.

Group II, claim(s) 18-19, drawn to a method for treating muscular dystrophy.

The inventions of groups I-II are found to have no special technical feature that defines a contribution over the prior art of Popplewell et al. (US 2012/0065244 A1).

Popplewell discloses SEQ ID NO:12 comprising the entire 28-mer of SEQ ID NO:2 claimed in the instant case. Therefore, applicant's invention does not contribute a special technical feature when viewed over the prior art of Popplewell et al. Accordingly, the inventions of groups I-II do not have a single inventive concept and so lack unity of invention, and therefore the restriction for examination purpose as indicated is proper.

Election of Species

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Application/Control Number: 14/776,533
Art Unit: 1674

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1. Applicant is required to elect a single antisense oligonucleotide species from SEQ ID NO:1-5.

2. Applicant is required to elect a single peptide species from SEQ ID NOs:16-31.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require all the limitations of an allowed generic claim. Currently, claims 1 and 16 are generic.

The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The antisense oligonucleotide and peptide species lack unity of invention because the species do not make a contribution over the prior art in view of Popplewell et al. (US 2012/0065244 A1), who disclosed SEQ ID NO:12 comprising SEQ ID NO:2 claimed in the instant case and "(R-Ahx-R)(4)", which corresponds to SEQ ID NO:27 claimed in the instant case. See paragraph 0032.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

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The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention or species.

Should applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), applicant must provide reasons in support thereof. Applicant may submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. Where such evidence or admission is provided by applicant, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be corrected in compliance with 37 CFR 1.48(a) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. A request to correct inventorship under 37 CFR 1.48(a) must be accompanied by an application data sheet in accordance with 37 CFR 1.76 that identifies each inventor by his or her legal name and by the processing fee required under 37 CFR 1.17(i).

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Notice of Rejoinder

The examiner has required restriction between product or apparatus claims and process claims. Where applicant elects claims directed to the product/apparatus, and all product/apparatus claims are subsequently found allowable, withdrawn process claims that include all the limitations of the allowable product/apparatus claims should be considered for rejoinder. All claims directed to a nonelected process invention must include all the limitations of an allowable product/apparatus claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product/apparatus claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product/apparatus are found allowable, an otherwise proper restriction requirement between product/apparatus claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product/apparatus claim will not be rejoined. See MPEP § 821.04. Additionally, in order for rejoinder to occur, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product/apparatus claims. **Failure to do so may result in no rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANA SHIN whose telephone number is (571)272-8008. The examiner can normally be reached on Monday through Thursday, 7am-5:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DANA SHIN/
Primary Examiner, Art Unit 1674



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

123147 7590 04/15/2016
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

EXAMINER	
CHONG, KIMBERLY	
ART UNIT	PAPER NUMBER

1674

DATE MAILED: 04/15/2016

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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14/852,090 09/11/2015 Stephen Donald Wilton AVN-008CN29RCE 2281

TITLE OF INVENTION: ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
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nonprovisional SMALL \$480 \$0 \$0 \$480 07/15/2016

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL
#: 36630

Complete and send this form, together with applicable fee(s), to: **Mail** **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

123147 7590 04/15/2016
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

14/852,090 09/11/2015 Stephen Donald Wilton AVN-008CN29RCE 2281

TITLE OF INVENTION: ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
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nonprovisional SMALL \$480 \$0 \$0 \$480 07/15/2016

EXAMINER	ART UNIT	CLASS-SUBCLASS
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CHONG, KIMBERLY 1674 536-024500

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

1 _____

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☐ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ Applicant certifying micro entity status. See 37 CFR 1.29
☐ Applicant asserting small entity status. See 37 CFR 1.27
☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/852,090	09/11/2015	Stephen Donald Wilton	AVN-008CN29RCE	2281

EXAMINER
CHONG, KIMBERLY

ART UNIT	PAPER NUMBER
1674	

DATE MAILED: 04/15/2016

123147 7590 04/15/2016
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 14/852,090	Applicant(s) WILTON ET AL.	
	Examiner KIMBERLY CHONG	Art Unit 1674	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 03/22/2016.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are 21 and 22. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a) ☐ All b) ☐ Some *c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date <u>03/22/2016</u> 3. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material 4. <input type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date _____ .	5. <input type="checkbox"/> Examiner's Amendment/Comment 6. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance 7. <input type="checkbox"/> Other _____.
---	---

/KIMBERLY CHONG/
Primary Examiner, Art Unit 1674

Application/Control Number: 14/852,090
Art Unit: 1674

Page 2

The present application is being examined under the pre-AIA first to invent provisions.

Information Disclosure Statement

The submission of the Information Disclosure Statement on 03/22/2016 is in compliance with 37 CFR 1.97. The information disclosure statement has been considered by the examiner and signed copies have been placed in the file.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Kimberly Chong** whose telephone number is **571-272-3111**. The examiner can normally be reached Monday thru Friday between 9-5 pm.

If attempts to reach the examiner by telephone are unsuccessful please contact the SPE for 1674 Shaojia Anna Jiang at 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has

Application/Control Number: 14/852,090
Art Unit: 1674

Page 3

been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Kimberly Chong/
Primary Examiner
Art Unit 1674



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

123147 7590 01/06/2016
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

EXAMINER	
CHONG, KIMBERLY	
ART UNIT	PAPER NUMBER

1674

DATE MAILED: 01/06/2016

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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14/852,090 09/11/2015 Stephen Donald Wilton AVN-008CN29 2281

TITLE OF INVENTION: ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$480	\$0	\$0	\$480	04/06/2016

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL
#: 36637

Complete and send this form, together with applicable fee(s), to: **Mail** **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

123147 7590 01/06/2016
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/852,090	09/11/2015	Stephen Donald Wilton	AVN-008CN29	2281

TITLE OF INVENTION: ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$480	\$0	\$0	\$480	04/06/2016

EXAMINER	ART UNIT	CLASS-SUBCLASS
CHONG, KIMBERLY	1674	536-024500

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
 2 _____
 3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☐ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ Applicant certifying micro entity status. See 37 CFR 1.29
☐ Applicant asserting small entity status. See 37 CFR 1.27
☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/852,090	09/11/2015	Stephen Donald Wilton	AVN-008CN29	2281

EXAMINER
CHONG, KIMBERLY

ART UNIT	PAPER NUMBER
1674	

DATE MAILED: 01/06/2016

123147 7590 01/06/2016
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 14/852,090	Applicant(s) WILTON ET AL.	
	Examiner KIMBERLY CHONG	Art Unit 1674	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 12/07/2015.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are 21 and 22. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a) ☐ All b) ☐ Some *c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

<ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date <u>See Continuation Sheet</u> 3. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material 4. <input type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date _____. 	<ol style="list-style-type: none"> 5. <input type="checkbox"/> Examiner's Amendment/Comment 6. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance 7. <input type="checkbox"/> Other _____.
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/KIMBERLY CHONG/
Primary Examiner, Art Unit 1674

Continuation Sheet (PTOL-37)

Application No. 14/852,090

Continuation of Attachment(s) 2. Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date: 12/01/2015,12/07/2015.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/852,090	09/11/2015	Stephen Donald Wilton	AVN-008CN29	2281

123147 7590 10/15/2015
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

EXAMINER

CHONG, KIMBERLY

ART UNIT	PAPER NUMBER
----------	--------------

1674

NOTIFICATION DATE	DELIVERY MODE
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10/15/2015

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipboston.docketing@nelsonmullins.com
chris.schlauch@nelsonmullins.com
ipqualityassuranceboston@nelsonmullins.com

Application No.
14/852,090
#: 86643Applicant(s)
WILTON ET AL.**Office Action Summary**Examiner
KIMBERLY CHONGArt Unit
1674AIA (First Inventor to File)
Status
No**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09/15/2015.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 21 and 22 is/are pending in the application.
 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 21 and 22 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 09/11/2015 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☒ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 11570691.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
 Paper No(s)/Mail Date 09/15/15, 09/17/15, 10/08/15.
- 3) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. ____.
- 4) ☐ Other: ____.

Application/Control Number: 14/852,090
Art Unit: 1674

Page 2

The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

Status of the Application

Claims 21 and 22 are pending and currently under examination. SEQ ID No. 175 is free of the prior art searched.

Information Disclosure Statement

The submission of the Information Disclosure Statements on 09/15/2015, 09/17/2015 and 10/08/2015 is in compliance with 37 CFR 1.97. The information disclosure statements have been considered by the examiner and signed copies have been placed in the file.

The information disclosure statements filed on 09/15/2015 having 8 pages fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because of the following reasons: The NPL documents having numbers 12 and 13 contained in the information disclosure statement filed 09/15/2015 have not been considered because the documents do not have the required date listed. The remaining documents have been considered and a signed copy has been placed in the file.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225

Application/Control Number: 14/852,090
Art Unit: 1674

Page 3

USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21 and 22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-47 of U.S. Patent No. 8,455,635. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of the patent are drawn to patently indistinguishable subject matter.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Kimberly Chong** whose telephone number is **571-272-3111**. The examiner can normally be reached Monday thru Friday between 9-5 pm.

If attempts to reach the examiner by telephone are unsuccessful please contact the SPE for 1674 Mark Shibuya at 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent

Application/Control Number: 14/852,090
Art Unit: 1674

Page 4

Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Kimberly Chong/
Primary Examiner
Art Unit 1674



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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NOTICE OF ALLOWANCE AND FEE(S) DUE

123147 7590 11/24/2015
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

EXAMINER	
CHONG, KIMBERLY	
ART UNIT	PAPER NUMBER

1674

DATE MAILED: 11/24/2015

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

14/852,149 09/11/2015 Stephen Donald Wilton AVN-008CN30 2680

TITLE OF INVENTION: ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$480	\$0	\$0	\$480	02/24/2016

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL
#: 36648

Complete and send this form, together with applicable fee(s), to: **Mail** **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

123147 7590 11/24/2015
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/852,149	09/11/2015	Stephen Donald Wilton	AVN-008CN30	2680

TITLE OF INVENTION: ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$480	\$0	\$0	\$480	02/24/2016

EXAMINER	ART UNIT	CLASS-SUBCLASS
CHONG, KIMBERLY	1674	536-024500

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
 2 _____
 3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☐ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ Applicant certifying micro entity status. See 37 CFR 1.29
☐ Applicant asserting small entity status. See 37 CFR 1.27
☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

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NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/852,149	09/11/2015	Stephen Donald Wilton	AVN-008CN30	2680

EXAMINER
CHONG, KIMBERLY

ART UNIT	PAPER NUMBER
1674	

DATE MAILED: 11/24/2015

123147 7590 11/24/2015
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

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The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 14/852,149	Applicant(s) WILTON ET AL.	
	Examiner KIMBERLY CHONG	Art Unit 1674	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 09/15/2015.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are 21-28. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
Certified copies:
a) ☒ All b) ☐ Some *c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 11/570,691.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date <u>See Continuation Sheet</u> 3. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material 4. <input type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date _____ .	5. <input type="checkbox"/> Examiner's Amendment/Comment 6. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance 7. <input type="checkbox"/> Other _____.
---	---

/KIMBERLY CHONG/
Primary Examiner, Art Unit 1674

Continuation Sheet (PTOL-37)

Application No. 14/852,149

Continuation of Attachment(s) 2. Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date: 09/15/15, 09/16/15, 10/8/15, 11/03/15.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

123147 7590 10/27/2015
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

EXAMINER	
MCDONALD, JENNIFER SUE PITRAK	
ART UNIT	PAPER NUMBER
1674	

DATE MAILED: 10/27/2015

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

14/852,257 09/11/2015 PETER SAZANI AVN-009DVCN1RCE 9708

TITLE OF INVENTION: MULTIPLE EXON SKIPPING COMPOSITIONS FOR DMD

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$480	\$0	\$0	\$480	01/27/2016

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

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IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL
#: 36654

Complete and send this form, together with applicable fee(s), to: **Mail** **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

123147 7590 10/27/2015
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/852,257	09/11/2015	PETER SAZANI	AVN-009DVCN1RCE	9708

TITLE OF INVENTION: MULTIPLE EXON SKIPPING COMPOSITIONS FOR DMD

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$480	\$0	\$0	\$480	01/27/2016

EXAMINER	ART UNIT	CLASS-SUBCLASS
MCDONALD, JENNIFER SUE PITRAK	1674	536-023100

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

1 _____

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
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4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

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Date _____

Typed or printed name _____

Registration No. _____



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UNITED STATES DEPARTMENT OF COMMERCE
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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/852,257	09/11/2015	PETER SAZANI	AVN-009DVCN1RCE	9708

EXAMINER
MCDONALD, JENNIFER SUE PITRAK

ART UNIT	PAPER NUMBER
1674	

DATE MAILED: 10/27/2015

123147 7590 10/27/2015
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

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(Applications filed on or after May 29, 2000)

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The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 14/852,257	Applicant(s) SAZANI ET AL.	
	Examiner JENNIFER PITRAK MCDONALD	Art Unit 1674	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to RCE filed 10/08/2015.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are 66-73. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a) ☐ All b) ☐ Some *c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

<ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____ 3. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material 4. <input type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date _____ 	<ol style="list-style-type: none"> 5. <input type="checkbox"/> Examiner's Amendment/Comment 6. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance 7. <input type="checkbox"/> Other _____
--	--

/JENNIFER PITRAK MCDONALD/
 Primary Examiner, Art Unit 1674



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

123147 7590 10/06/2015
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

EXAMINER	
MCDONALD, JENNIFER SUE PITRAK	
ART UNIT	PAPER NUMBER
1674	

DATE MAILED: 10/06/2015

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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14/852,257 09/11/2015 PETER SAZANI AVN-009DVCN1 9708

TITLE OF INVENTION: MULTIPLE EXON SKIPPING COMPOSITIONS FOR DMD

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$480	\$0	\$0	\$480	01/06/2016

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL
#: 36659

Complete and send this form, together with applicable fee(s), to: **Mail** **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

123147 7590 10/06/2015
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/852,257	09/11/2015	PETER SAZANI	AVN-009DVCN1	9708

TITLE OF INVENTION: MULTIPLE EXON SKIPPING COMPOSITIONS FOR DMD

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$480	\$0	\$0	\$480	01/06/2016

EXAMINER	ART UNIT	CLASS-SUBCLASS
MCDONALD, JENNIFER SUE PITRAK	1674	536-023100

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

1 _____

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ Applicant certifying micro entity status. See 37 CFR 1.29
- ☐ Applicant asserting small entity status. See 37 CFR 1.27
- ☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/852,257	09/11/2015	PETER SAZANI	AVN-009DVCN1	9708

EXAMINER
MCDONALD, JENNIFER SUE PITRAK

ART UNIT	PAPER NUMBER
1674	

DATE MAILED: 10/06/2015

123147 7590 10/06/2015
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

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1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
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9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 14/852,257		Applicant(s) SAZANI ET AL.	
	Examiner JENNIFER PITRAK MCDONALD		Art Unit 1674	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to CLAIMS FILED 09/15/2015.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are 66-73. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a) ☐ All b) ☐ Some *c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date ____ 3. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material 4. <input type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date ____	5. <input type="checkbox"/> Examiner's Amendment/Comment 6. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 7. <input type="checkbox"/> Other ____
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Application/Control Number: 14/852,257
Art Unit: 1674

Page 2

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance: the instant application is a continuation (CON) of 14/523610, which is a divisional (DIV) of 12/605276, now patent 8871918. The instant claims are free of the prior art and are deemed in condition for allowance.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER PITRAK MCDONALD whose telephone number is (571)270-3061. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JENNIFER PITRAK MCDONALD/
Primary Examiner, Art Unit 1674



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

123147 7590 04/21/2016
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

EXAMINER	
MCDONALD, JENNIFER SUE PITRAK	
ART UNIT	PAPER NUMBER
1674	

DATE MAILED: 04/21/2016

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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14/852,264 09/11/2015 Peter Sazani AVN-009DVCN2 3499

TITLE OF INVENTION: MULTIPLE EXON SKIPPING COMPOSITIONS FOR DMD

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$480	\$0	\$0	\$480	07/21/2016

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL
#: 36665

Complete and send this form, together with applicable fee(s), to: **Mail** **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

123147 7590 04/21/2016
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/852,264	09/11/2015	Peter Sazani	AVN-009DVCN2	3499

TITLE OF INVENTION: MULTIPLE EXON SKIPPING COMPOSITIONS FOR DMD

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$480	\$0	\$0	\$480	07/21/2016

EXAMINER	ART UNIT	CLASS-SUBCLASS
MCDONALD, JENNIFER SUE PITRAK	1674	536-023100

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

1 _____

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ Applicant certifying micro entity status. See 37 CFR 1.29
- ☐ Applicant asserting small entity status. See 37 CFR 1.27
- ☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/852,264	09/11/2015	Peter Sazani	AVN-009DVCN2	3499

EXAMINER
MCDONALD, JENNIFER SUE PITRAK

ART UNIT	PAPER NUMBER
1674	

DATE MAILED: 04/21/2016

123147 7590 04/21/2016
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 14/852,264	Applicant(s) SAZANI ET AL.	
	Examiner JENNIFER PITRAK MCDONALD	Art Unit 1674	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 1/21/2016.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are 66-73. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a) ☐ All b) ☐ Some *c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

<ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____ 3. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material 4. <input type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date _____ 	<ol style="list-style-type: none"> 5. <input type="checkbox"/> Examiner's Amendment/Comment 6. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 7. <input type="checkbox"/> Other _____
--	---

/JENNIFER PITRAK MCDONALD/ Primary Examiner, Art Unit 1674	
---	--

Application/Control Number: 14/852,264
Art Unit: 1674

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The present application is being examined under the pre-AIA first to invent provisions.

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance:

Applicant's argument regarding the availability of Moulton, et al. (US 2010/0016215) as prior art under 35 USC § 102(e), presented at page 5 of Applicant's 01/21/2016 response, is persuasive. Therefore, the rejection of claims under 35 USC § 102(e) as being anticipated by Moulton, et al. (US 2010/0016215) is withdrawn.

Applicant's arguments traversing the rejection of claims 66-73 under 35 USC § 103(a) over Matsuo, et al. (US 2007/0082861), Wilton, et al. (WO 2006/000057), Venter, et al. (US 2007/0037165), and Baracchini, et al. (U.S. Patent 5801154) are found persuasive. Therefore, the rejection is withdrawn.

The rejection of claims 66-73 on the ground of nonstatutory double patenting as being unpatentable over claims 1-38 of U.S. Patent 8871918 in view of Wilton, et al. (WO 2006/000057), Venter, et al. (US 2007/0037165), and Baracchini, et al. (U.S. Patent 5801154) is withdrawn.

Claims 66-73 are allowed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER PITRAK MCDONALD whose telephone number is

Application/Control Number: 14/852,264
Art Unit: 1674

Page 3

(571)270-3061. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia (Anna) Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JENNIFER PITRAK MCDONALD/
Primary Examiner, Art Unit 1674



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/852,264	09/11/2015	Peter Sazani	AVN-009DVCN2	3499

123147 7590 10/21/2015
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

EXAMINER

MCDONALD, JENNIFER SUE PITRAK

ART UNIT	PAPER NUMBER
----------	--------------

1674

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

10/21/2015

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipboston.docketing@nelsonmullins.com
chris.schlauch@nelsonmullins.com
ipqualityassuranceboston@nelsonmullins.com

Application No.
14/852,264
#: 86672Applicant(s)
SAZANI ET AL.**Office Action Summary**Examiner
JENNIFER PITRAK MCDONALDArt Unit
1674AIA (First Inventor to File)
Status
No**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/15/2015.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 66-73 is/are pending in the application.
 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 66-73 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
 Paper No(s)/Mail Date ____.
- 3) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. ____.
- 4) ☐ Other: ____.

Application/Control Number: 14/852,264
Art Unit: 1674

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DETAILED ACTION

Remarks

The present application is being examined under the pre-AIA first to invent provisions. Claims 66-73 are currently pending and are under examination.

Priority

The instant application is a continuation (CON) of Application 14/523610, which is a divisional (DIV) of Application 12/605276 (now U.S. Patent 8871918), which claims priority to provisional application 61/108416, filed 10/24/2008. All prior-filed applications are deemed to provide adequate support or enablement in the manner provided by 35 U.S.C. 112(a) or pre-AIA 35 U.S.C. 112, first paragraph for claims 66-73 of this application. Therefore, the instant claims 66-73 are accorded the benefit of the filing date of Application No. 61/108416, which is 10/24/2008.

Claim Rejections - 35 USC § 112

The following is a quotation of 35 U.S.C. 112(b):

(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 66-73 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject

Application/Control Number: 14/852,264
Art Unit: 1674

Page 3

matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

Each of claims 66-69 recite the phrase, "thymine bases are uracil bases". This phrase renders the claims indefinite because a thymine base cannot be a uracil base.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of pre-AIA 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 66-73 are rejected under pre-AIA 35 U.S.C. 102(e) as being anticipated by Moulton, et al. (US 2010/0016215 A1, filing date June 29, 2007)(cited by Applicant).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under pre-AIA 35 U.S.C. 102(e). This rejection under pre-AIA 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131(a).

Moulton teaches a composition as instantly claimed. See at least abstract; paragraphs [0042], [0052] - [0056]; SEQ ID NO:34, claims.

Therefore, Moulton anticipates the instant claims 66-73.

Application/Control Number: 14/852,264
Art Unit: 1674

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Claim Rejections - 35 USC § 103

Matsuo, et al., Wilton, et al., and Venter, et al.

Claims 66 -73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsuo, et al. (US 2007/0082861)(cited on Applicant's IDS), Wilton, et al. (WO 2006/000057, cited on Applicant's IDS), Venter, et al. (US 2007/0037165, cited on Applicant's IDS), and Baracchini, et al. (US Patent 5801154).

The claims are directed to an antisense oligonucleotide comprising 21 nucleotides, including 17 consecutive bases of SEQ ID NO: 285 and having modifications including 5-methylcytosine, 2'-O-methyl sugar modification, and/or hypoxanthine bases, wherein the oligonucleotide is useful for producing exon skipping of exon 50 in processing of human dystrophin mRNA.

Matsuo, et al. and Wilton, et al. teach antisense oligonucleotides for producing exon skipping of exon 50 in processing of human dystrophin mRNA. Matsuo, et al. teach an antisense oligonucleotide targeting dystrophin (p.91, paragraphs 756-757; SEQ ID NO:45). This antisense oligonucleotide comprises 18 of 25 nucleotides of the instantly claimed antisense oligonucleotide having SEQ ID NO:285 as shown (shared nucleotides are underlined).

Matsuo, et al.	5' - <u>GCTCCAATAGTGGTCAGT</u> -3'
SEQ ID NO: 285	5' -AG <u>GCTCCAATAGTGGTCAGT</u> CCAGG-3'

Wilton, et al. teach antisense oligonucleotides for producing exon skipping of exon 50 in processing of human dystrophin mRNA. Wilton, et al. teach that the antisense oligonucleotides

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may preferably be between 17-30 nucleotides in length (p.24, second paragraph) and that the antisense oligonucleotides may be morpholino antisense oligonucleotides (see description for Table 1A spanning pages 16 and 17). Wilton, et al. exemplify antisense oligonucleotides that are 25 nucleotides in length (table starting at page 10). Wilton, et al. teach antisense molecules comprising modifications including 2'-O-methyl groups, uracil bases, and 5-methylcytosine bases.

Venter, et al. teach the human dystrophin (DMD) sequence. See SEQ ID NO:14546, for example. Matsuo's antisense oligonucleotide corresponds to the DMD sequence as shown.

Matsuo, et al.	5'	GCTCCAATAGTGGTCAGT	3'
Venter, et al.	3' (113967)	GAATGTCCGAGGTTATCACCAGTCAGGTCC	(113938) 5'

Baracchini teaches that antisense oligonucleotides typically comprise nucleobase modifications or substitutions, such as hypoxanthine, inosine, and 5-me-C.

It would have been obvious to one of skill in the art at the time the instant invention was made to make an antisense oligonucleotide targeting exon 50 of the human dystrophin gene because Matsuo, et al. and Wilton, et al. teach such oligonucleotides. It would have been obvious to make the antisense oligonucleotide having the sequence 5'-GCTCCAATAGTGGTCAGT-3' for exon skipping, because Matsuo, et al. teach such an oligonucleotide. It further would have been obvious to extend the oligonucleotide in either the 5'- or 3'-direction to incorporate up to 30 nucleotides because Wilton, et al. suggest that the antisense oligonucleotides comprise up to 30 nucleotides. Extension of Matsuo's antisense oligonucleotide by just 3 nucleotides in the 3'-direction would yield an antisense oligonucleotide

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consisting of 21 consecutive nucleotides of the instantly claimed SEQ ID NO:285. It further would have been obvious to make the oligonucleotide with modifications such as 2'-O-methyl groups and 5-methylcytosine and hypoxanthine because such modifications were well-known and used by those of skill in the antisense oligonucleotide art. Therefore, the instant claims would have been *prima facie* obvious to one of skill in the art at the time of the instant invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope

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of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP §§ 706.02(1)(1) - 706.02(1)(3) for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/forms/. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to <http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp>.

8871918

Claims 66-73 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-38 of U.S. Patent No. 8871918 in view of Wilton, et al. (WO 2006/000057, cited on Applicant's IDS), Venter, et al. (US 2007/0037165, cited on Applicant's IDS), and Baracchini, et al. (US Patent 5801154).

The claims are directed to an antisense oligonucleotide comprising 17 consecutive bases of SEQ ID NO: 285 and having modifications including 5-methylcytosine, 2'-O-methyl sugar modification, and/or hypoxanthine bases, wherein the oligonucleotide is useful for producing exon skipping of exon 50 in processing of human dystrophin mRNA.

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The patent is directed to an antisense oligonucleotide and methods of use thereof, comprising SEQ ID NO:287. SEQ ID NO:287 overlaps with the instantly claimed SEQ ID NO:285 as shown:

```
SEQ ID NO: 287    5'-CTTACAGGCTCCAATAGTGGTCAGT-3'
SEQ ID NO: 285    5'-AGGCTCCAATAGTGGTCAGTCCAGG-3'
```

Wilton, et al. teach antisense oligonucleotides for producing exon skipping of exon 50 in processing of human dystrophin mRNA. Wilton, et al. teach that the antisense oligonucleotides may preferably be between 17-30 nucleotides in length (p.24, second paragraph) and that the antisense oligonucleotides may be morpholino antisense oligonucleotides (see description for Table 1A spanning pages 16 and 17). Wilton, et al. exemplify antisense oligonucleotides that are 21 nucleotides in length (table starting at page 10). Wilton, et al. teach antisense molecules comprising modifications including 2'-O-methyl groups, uracil bases, and 5-methylcytosine bases.

Venter, et al. teach the human dystrophin (DMD) sequence. See SEQ ID NO:14546, for example. The patented antisense oligonucleotide corresponds to the DMD sequence as shown.

```
SEQ ID NO:287    5'-CTTACAGGCTCCAATAGTGGTCAGT-3'
                  |||
Venter, et al.  3' (113967) GAATGTCCGAGGTTATCACCAGTCAGGTCC (113938) 5'
```

Baracchini teaches that antisense oligonucleotides typically comprise nucleobase modifications or substitutions, such as hypoxanthine, inosine, and 5-me-C.

It would have been obvious to one of skill in the art at the time the instant invention was made to make the instantly claimed antisense oligonucleotide targeting exon 50 of the human

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Art Unit: 1674

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dystrophin gene because the patent teaches an AON comprising 21 nucleotides including 17 consecutive nucleotides of the instantly claimed SEQ ID NO:285. It would have been obvious to make the oligonucleotide with modifications such as 2'-O-methyl groups and 5-methylcytosine and hypoxanthine because such modifications were well-known and used by those of skill in the antisense oligonucleotide art. Therefore, the instant claims are deemed unpatentable over the claims of U.S. Patent 8871918.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER PITRAK MCDONALD whose telephone number is (571)270-3061. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JENNIFER PITRAK MCDONALD/
Primary Examiner, Art Unit 1674



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

123147 7590 04/12/2016
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

EXAMINER	
CHONG, KIMBERLY	
ART UNIT	PAPER NUMBER

1674

DATE MAILED: 04/12/2016

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/657,555	09/17/2015	Stephen Donald Wilton	AVN-008CN31	6627

TITLE OF INVENTION: ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$480	\$0	\$0	\$480	07/12/2016

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL
#: 36682Complete and send this form, together with applicable fee(s), to: MailMail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

123147 7590 04/12/2016
Nelson Mullins Riley & Scarborough LLP/Sarepta
One Post Office Square
Boston, MA 02109

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/857,555	09/17/2015	Stephen Donald Wilton	AVN-008CN31	6627

TITLE OF INVENTION: ANTISENSE OLIGONUCLEOTIDES FOR INDUCING EXON SKIPPING AND METHODS OF USE THEREOF

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$480	\$0	\$0	\$480	07/12/2016

EXAMINER	ART UNIT	CLASS-SUBCLASS
CHONG, KIMBERLY	1674	536-024500

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ Applicant certifying micro entity status. See 37 CFR 1.29
- ☐ Applicant asserting small entity status. See 37 CFR 1.27
- ☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/857,555	09/17/2015	Stephen Donald Wilton	AVN-008CN31	6627
123147 7590 04/12/2016 Nelson Mullins Riley & Scarborough LLP/Sarepta One Post Office Square Boston, MA 02109			EXAMINER CHONG, KIMBERLY	
			ART UNIT	PAPER NUMBER
			1674	
DATE MAILED: 04/12/2016				

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 14/857,555	Applicant(s) WILTON ET AL.	
	Examiner KIMBERLY CHONG	Art Unit 1674	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 02/05/2016.
☐ A declaration(s)/affidavit(s) under 37 CFR 1.130(b) was/were filed on _____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are 21-24. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a) ☐ All b) ☐ Some *c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

<ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date <u>11/03/2015, 02/05/2016</u> 3. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material 4. <input type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date _____. 	<ol style="list-style-type: none"> 5. <input type="checkbox"/> Examiner's Amendment/Comment 6. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 7. <input type="checkbox"/> Other _____.
---	--

/KIMBERLY CHONG/
Primary Examiner, Art Unit 1674

Application/Control Number: 14/857,555
Art Unit: 1674

Page 2

The present application is being examined under the pre-AIA first to invent provisions.

The following is an examiner's statement of reasons for allowance:

The terminal disclaimer filed 02/05/2016 has been approved and thus the Double Patenting rejection is overcome.

The IDS filed 02/05/2016 has been considered.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Kimberly Chong** whose telephone number is **571-272-3111**. The examiner can normally be reached Monday thru Friday between 9-5 pm.

If attempts to reach the examiner by telephone are unsuccessful please contact the SPE for 1674 Shaojia Anna Jiang at 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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